Dokumentvorlage, Version vom 16.12.2021

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Avapritinib (AYVAKYT®)

Blueprint Medicines (Germany) GmbH,
a Sanofi Company

Modul 4 A – Anhang 4-G

Avapritinib (AYVAKYT®) ist zur Behandlung erwachsener Patienten mit indolenter systemischer Mastozytose (ISM) mit mittelschweren bis schweren Symptomen indiziert, bei denen mit einer symptomatischen Behandlung keine ausreichende Kontrolle erzielt werden kann.

Medizinischer Nutzen und
medizinischer Zusatznutzen,
Patientengruppen mit therapeutisch
bedeutsamem Zusatznutzen

Stand: 30.10.2025

Anhang 4-G: Weitere Analysen und graphische Verläufe zu den in Abschnitt 4.3.1.3.2 gezeigten Ergebnissen der Subgruppenanalysen

Seite

Studienergebnisse 3

Subgruppenanalysen 3

Weitere Analysen – nicht-signifikante p-Interaktionsterme 3

Morbidität 3

Krankheitsspezifische Symptomatik gemäß ISM-SAF 3

Veränderung der Serum-Tryptasekonzentration 1017

Veränderung der KIT-D816V-MAF im Blut 1062

Veränderung des Anteils der Mastzellen im Knochenmark 1114

EQ-5D-5L VAS 1138

Schwere der Erkrankung gemäß PGIC/PGIS 1197

Veränderung im Gebrauch von BSC 1348

Anaphylaxie-Episoden mit Epinephrin-Einsatz 1353

Mastozytose auf der Haut 1358

Gesundheitsbezogene Lebensqualität 1488

MC-QoL 1488

SF-12 3241

Sicherheit 3787

Unerwünschte Ereignisse 3787

Graphische Verläufe – signifikante p-Interaktionsterme 4751

Altersgruppe 4751

Geschlecht 4771

Region 4775

ISM-Status zur Baseline 4779

Serum-Tryptasekonzentration zur Baseline 4781

ECOG PS Status	4793
Vorherige TKI-Therapie	4795

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	130	11	9	
Mean (StdDev)	54.26 (20.669)	50.26 (19.201)	42.42 (9.984)	48.85 (19.376)	
Median	48.91	48.05	39.36	44.14	
Min, Max	18.0, 104.4	12.1, 102.7	31.0, 61.7	18.9, 76.8	

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	59	124	11	9	
Mean (StdDev)	48.09 (20.536)	42.84 (19.194)	39.02 (11.167)	38.27 (20.417)	
Median	43.79	39.98	35.54	41.36	
Min, Max	12.9, 98.9	12.4, 92.3	23.5, 58.9	10.9, 69.4	
C2D1 CFB					
n	59	122	11	9	
LS Mean (StdErr) [2]	-5.78 (1.190)	-7.39 (0.899)	-5.15 (3.002)	-13.56 (3.808)	
95% CI [2]	-8.13, -3.44	-9.16, -5.62	-11.51, 1.22	-21.64, -5.49	
Difference (95% CI) in CFB [2]		-1.60 (-4.25, 1.04)		-8.42 (-14.35, -2.48)	
p-value [3]		0.233		0.008	

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	60	125	11	9	
Mean (StdDev)	45.23 (20.862)	39.33 (19.374)	37.26 (12.842)	33.03 (20.333)	
Median	43.46	38.43	34.93	26.36	
Min, Max	6.5, 93.8	8.9, 91.9	18.5, 61.6	8.8, 72.4	
C3D1 CFB					
n	60	123	11	9	
LS Mean (StdErr) [2]	-7.85 (1.596)	-10.62 (1.191)	-7.40 (4.765)	-19.26 (6.044)	
95% CI [2]	-11.00, -4.70	-12.98, -8.27	-17.50, 2.70	-32.07, -6.45	
Difference (95% CI) in CFB [2]		-2.78 (-6.32, 0.77)		-11.87 (-21.28, -2.45)	
p-value [3]		0.124		0.017	

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	58	124	10	9	
Mean (StdDev)	44.83 (21.597)	37.63 (19.953)	37.58 (12.391)	29.17 (21.649)	
Median	40.08	36.17	37.56	23.36	
Min, Max	7.3, 90.0	4.1, 92.2	15.5, 56.9	4.9, 70.8	
C4D1 CFB					
n	58	122	10	9	
LS Mean (StdErr) [2]	-8.61 (1.860)	-12.60 (1.369)	-6.27 (5.715)	-20.66 (7.195)	
95% CI [2]	-12.28, -4.94	-15.30, -9.90	-18.45, 5.91	-35.99, -5.32	
Difference (95% CI) in CFB [2]		-3.99 (-8.09, 0.11)		-14.39 (-25.80, -2.97)	
p-value [3]		0.056		0.017	

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	57	127	9	9	
Mean (StdDev)	44.12 (22.134)	36.43 (19.688)	40.45 (10.449)	24.62 (22.137)	
Median	41.43	33.92	36.29	19.14	
Min, Max	6.6, 90.0	3.8, 89.6	28.9, 57.5	1.3, 73.1	
C5D1 CFB					
n	57	125	9	9	
LS Mean (StdErr) [2]	-9.10 (1.998)	-13.41 (1.441)	-5.00 (6.026)	-26.20 (7.515)	
95% CI [2]	-13.04, -5.15	-16.26, -10.57	-17.92, 7.93	-42.32, -10.08	
Difference (95% CI) in CFB [2]		-4.32 (-8.72, 0.08)		-21.20 (-33.39, -9.02)	
p-value [3]		0.055		0.002	

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	124	10	9	
Mean (StdDev)	41.53 (20.772)	34.73 (19.929)	37.50 (13.392)	24.74 (22.621)	
Median	39.10	32.04	37.63	16.43	
Min, Max	5.3, 83.4	3.3, 100.6	9.4, 57.1	1.5, 74.5	
C6D1 CFB					
n	54	122	10	9	
LS Mean (StdErr) [2]	-10.19 (2.137)	-14.65 (1.551)	-6.36 (6.334)	-24.75 (7.975)	
95% CI [2]	-14.41, -5.97	-17.71, -11.59	-19.86, 7.14	-41.75, -7.76	
Difference (95% CI) in CFB [2]		-4.46 (-9.18, 0.26)		-18.39 (-31.04, -5.74)	
p-value [3]		0.064		0.007	

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	55	121	10	9	
Mean (StdDev)	42.83 (22.179)	34.09 (19.869)	39.53 (13.506)	25.25 (21.970)	
Median	40.08	32.36	36.79	19.21	
Min, Max	5.5, 86.1	3.7, 103.5	16.3, 59.2	0.9, 73.1	
C7D1 CFB					
n	55	119	10	9	
LS Mean (StdErr) [2]	-10.07 (2.191)	-15.14 (1.583)	-5.63 (6.953)	-25.24 (8.755)	
95% CI [2]	-14.40, -5.75	-18.26, -12.01	-20.45, 9.19	-43.91, -6.58	
Difference (95% CI) in CFB [2]		-5.07 (-9.92, -0.21)		-19.62 (-33.50, -5.73)	
Hedges'G (95% CI) in CFB		-0.30 (-0.62, 0.02)		-0.78 (-1.90, 0.13)	
p-value [3]		0.041		0.009	
					0.080

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	17	41	54	98	
Mean (StdDev)	54.00 (23.600)	43.87 (17.753)	51.93 (18.703)	52.80 (19.175)	
Median	43.36	40.54	47.93	50.62	
Min, Max	18.5, 86.3	17.6, 102.7	18.0, 104.4	12.1, 98.4	

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	54	94	
Mean (StdDev)	46.84 (21.303)	39.23 (18.105)	46.61 (19.262)	43.90 (19.612)	
Median	41.54	36.17	43.03	41.36	
Min, Max	12.9, 79.6	10.9, 89.4	14.8, 98.9	12.4, 92.3	
C2D1 CFB					
n	16	39	54	92	
LS Mean (StdErr) [2]	-8.50 (1.961)	-5.58 (1.326)	-4.67 (1.293)	-8.44 (1.108)	
95% CI [2]	-12.44, -4.57	-8.24, -2.92	-7.23, -2.12	-10.63, -6.25	
Difference (95% CI) in CFB [2]		2.92 (-1.54, 7.39)		-3.77 (-6.62, -0.92)	
p-value [3]		0.195		0.010	

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	39	54	95	
Mean (StdDev)	42.44 (23.318)	36.35 (16.400)	44.49 (19.015)	39.95 (20.526)	
Median	39.93	36.14	41.61	39.57	
Min, Max	6.5, 84.6	8.8, 86.6	13.9, 93.8	8.9, 91.9	
C3D1 CFB					
n	17	39	54	93	
LS Mean (StdErr) [2]	-11.86 (2.420)	-8.20 (1.673)	-6.37 (1.793)	-12.12 (1.501)	
95% CI [2]	-16.71, -7.00	-11.56, -4.84	-9.91, -2.83	-15.08, -9.15	
Difference (95% CI) in CFB [2]		3.66 (-1.86, 9.17)		-5.75 (-9.70, -1.80)	
p-value [3]		0.189		0.005	

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	17	39	51	94	
Mean (StdDev)	41.27 (24.834)	34.42 (17.079)	44.59 (19.188)	38.15 (21.213)	
Median	37.29	32.86	39.29	37.68	
Min, Max	7.3, 83.5	9.0, 85.0	14.5, 90.0	4.1, 92.2	
C4D1 CFB					
n	17	39	51	92	
LS Mean (StdErr) [2]	-12.82 (2.878)	-9.96 (1.990)	-6.69 (2.102)	-14.29 (1.722)	
95% CI [2]	-18.60, -7.05	-13.95, -5.96	-10.85, -2.53	-17.70, -10.89	
Difference (95% CI) in CFB [2]		2.87 (-3.69, 9.43)		-7.60 (-12.18, -3.03)	
p-value [3]		0.384		0.001	

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	39	49	97	
Mean (StdDev)	41.80 (24.329)	32.58 (16.526)	44.25 (19.826)	36.89 (21.173)	
Median	39.36	31.57	41.08	34.29	
Min, Max	6.6, 79.9	9.7, 78.8	10.8, 90.0	1.3, 89.6	
C5D1 CFB					
n	17	39	49	95	
LS Mean (StdErr) [2]	-11.34 (2.931)	-10.93 (2.027)	-7.25 (2.336)	-15.36 (1.840)	
95% CI [2]	-17.22, -5.46	-15.00, -6.87	-11.87, -2.63	-18.99, -11.72	
Difference (95% CI) in CFB [2]		0.41 (-6.27, 7.09)		-8.10 (-13.18, -3.03)	
p-value [3]		0.902		0.002	

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	17	38	47	95	
Mean (StdDev)	41.15 (23.047)	31.62 (16.137)	40.82 (18.719)	35.02 (21.594)	
Median	39.29	29.99	38.71	31.43	
Min, Max	5.3, 82.5	8.2, 81.9	9.4, 83.4	1.5, 100.6	
C6D1 CFB					
n	17	38	47	93	
LS Mean (StdErr) [2]	-12.52 (3.335)	-12.57 (2.371)	-8.43 (2.420)	-16.13 (1.936)	
95% CI [2]	-19.22, -5.83	-17.33, -7.81	-13.21, -3.64	-19.96, -12.30	
Difference (95% CI) in CFB [2]		-0.04 (-7.66, 7.57)		-7.70 (-13.00, -2.40)	
p-value [3]		0.991		0.005	

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	17	39	48	91	
Mean (StdDev)	41.55 (23.461)	31.75 (15.527)	42.59 (20.356)	34.23 (21.747)	
Median	41.00	29.29	37.82	33.43	
Min, Max	9.2, 86.1	12.5, 80.9	5.5, 85.6	0.9, 103.5	
C7D1 CFB					
n	17	39	48	89	
LS Mean (StdErr) [2]	-12.17 (3.446)	-12.34 (2.383)	-8.21 (2.488)	-17.13 (1.989)	
95% CI [2]	-19.08, -5.25	-17.12, -7.56	-13.13, -3.29	-21.06, -13.20	
Difference (95% CI) in CFB [2]		-0.17 (-8.03, 7.68)		-8.92 (-14.38, -3.46)	
Hedges'G (95% CI) in CFB		-0.01 (-0.59, 0.57)		-0.49 (-0.85, -0.14)	
p-value [3]		0.965		0.002	
					0.085

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	33	58	38	81	
Mean (StdDev)	53.98 (20.404)	50.59 (19.800)	51.08 (19.476)	49.86 (18.780)	
Median	48.43	46.21	46.07	48.71	
Min, Max	18.0, 104.4	17.6, 102.7	18.5, 87.3	12.1, 98.4	

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	32	59	38	74	
Mean (StdDev)	47.38 (20.801)	44.42 (18.538)	46.06 (18.765)	41.02 (19.764)	
Median	41.67	41.36	43.36	37.14	
Min, Max	14.8, 98.9	13.9, 92.3	12.9, 81.4	10.9, 89.6	
C2D1 CFB					
n	32	57	38	74	
LS Mean (StdErr) [2]	-7.73 (1.430)	-7.76 (1.187)	-3.79 (1.551)	-7.51 (1.200)	
95% CI [2]	-10.57, -4.89	-10.12, -5.40	-6.86, -0.71	-9.89, -5.14	
Difference (95% CI) in CFB [2]		-0.02 (-3.28, 3.23)		-3.73 (-7.16, -0.29)	
p-value [3]		0.988		0.034	

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	33	58	38	76	
Mean (StdDev)	46.09 (20.555)	40.32 (18.278)	42.18 (19.540)	37.83 (20.310)	
Median	43.00	38.89	40.46	35.43	
Min, Max	13.9, 93.8	11.2, 91.9	6.5, 78.4	8.8, 86.6	
C3D1 CFB					
n	33	56	38	76	
LS Mean (StdErr) [2]	-8.24 (1.953)	-11.40 (1.637)	-7.28 (2.127)	-10.70 (1.601)	
95% CI [2]	-12.13, -4.36	-14.66, -8.15	-11.50, -3.07	-13.87, -7.53	
Difference (95% CI) in CFB [2]		-3.16 (-7.61, 1.29)		-3.41 (-8.12, 1.29)	
p-value [3]		0.161		0.153	

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	31	58	37	75	
Mean (StdDev)	44.56 (21.312)	37.76 (19.183)	43.09 (20.244)	36.52 (20.890)	
Median	37.93	38.60	39.00	34.08	
Min, Max	12.5, 90.0	4.1, 92.2	7.3, 83.5	4.9, 92.0	
C4D1 CFB					
n	31	56	37	75	
LS Mean (StdErr) [2]	-10.90 (2.476)	-14.66 (2.005)	-6.35 (2.331)	-12.10 (1.750)	
95% CI [2]	-15.83, -5.98	-18.64, -10.67	-10.97, -1.73	-15.57, -8.64	
Difference (95% CI) in CFB [2]		-3.75 (-9.27, 1.77)		-5.75 (-10.91, -0.60)	
p-value [3]		0.180		0.029	

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	30	59	36	77	
Mean (StdDev)	45.13 (23.515)	35.94 (18.608)	42.36 (18.709)	35.43 (21.102)	
Median	40.46	33.15	40.86	33.00	
Min, Max	9.6, 90.0	8.8, 89.6	6.6, 79.9	1.3, 84.6	
C5D1 CFB					
n	30	57	36	77	
LS Mean (StdErr) [2]	-10.43 (2.635)	-16.11 (2.058)	-6.60 (2.580)	-12.55 (1.906)	
95% CI [2]	-15.67, -5.18	-20.20, -12.02	-11.71, -1.49	-16.33, -8.78	
Difference (95% CI) in CFB [2]		-5.68 (-11.57, 0.20)		-5.95 (-11.65, -0.26)	
p-value [3]		0.058		0.041	

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	29	57	35	76	
Mean (StdDev)	42.73 (21.755)	34.64 (18.151)	39.39 (18.142)	33.61 (21.694)	
Median	38.55	31.23	38.86	31.24	
Min, Max	10.2, 83.4	3.3, 93.4	5.3, 74.5	1.5, 100.6	
C6D1 CFB					
n	29	55	35	76	
LS Mean (StdErr) [2]	-11.47 (2.921)	-16.98 (2.332)	-8.36 (2.600)	-14.02 (1.937)	
95% CI [2]	-17.29, -5.66	-21.62, -12.34	-13.51, -3.20	-17.86, -10.18	
Difference (95% CI) in CFB [2]		-5.50 (-12.06, 1.06)		-5.66 (-11.40, 0.08)	
p-value [3]		0.099		0.053	

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	30	55	35	75	
Mean (StdDev)	43.54 (24.165)	33.14 (18.091)	41.28 (18.214)	33.73 (21.500)	
Median	39.21	31.29	38.21	31.50	
Min, Max	5.5, 86.1	5.8, 93.6	9.2, 81.8	0.9, 103.5	
C7D1 CFB					
n	30	53	35	75	
LS Mean (StdErr) [2]	-12.00 (2.983)	-18.58 (2.413)	-7.19 (2.697)	-13.66 (1.970)	
95% CI [2]	-17.93, -6.06	-23.38, -13.78	-12.53, -1.84	-17.57, -9.76	
Difference (95% CI) in CFB [2]		-6.58 (-13.33, 0.16)		-6.47 (-12.43, -0.52)	
Hedges'G (95% CI) in CFB		-0.38 (-0.85, 0.07)		-0.38 (-0.80, 0.02)	
p-value [3]		0.055		0.033	
					0.997

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	26	52	45	87	
Mean (StdDev)	33.64 (6.869)	31.70 (7.002)	63.28 (16.409)	61.21 (15.153)	
Median	35.14	33.86	60.00	56.93	
Min, Max	18.0, 41.3	12.1, 41.4	42.1, 104.4	42.4, 102.7	

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	26	49	44	82	
Mean (StdDev)	30.03 (7.841)	26.21 (8.109)	56.50 (17.708)	51.94 (17.412)	
Median	29.75	25.83	52.57	47.84	
Min, Max	12.9, 46.1	10.9, 46.4	25.4, 98.9	17.4, 92.3	
C2D1 CFB					
n	26	49	44	82	
LS Mean (StdErr) [2]	-3.66 (1.264)	-5.21 (0.939)	-7.56 (1.521)	-9.92 (1.257)	
95% CI [2]	-6.18, -1.14	-7.08, -3.34	-10.58, -4.55	-12.41, -7.43	
Difference (95% CI) in CFB [2]		-1.54 (-4.33, 1.24)		-2.36 (-5.87, 1.16)	
p-value [3]		0.273		0.187	

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	26	49	45	83	
Mean (StdDev)	28.39 (10.322)	24.73 (10.360)	53.02 (18.621)	46.92 (18.848)	
Median	27.49	24.21	51.79	45.50	
Min, Max	6.5, 46.4	8.8, 59.4	14.8, 93.8	8.9, 91.9	
C3D1 CFB					
n	26	49	45	83	
LS Mean (StdErr) [2]	-5.98 (1.918)	-7.23 (1.425)	-10.26 (1.982)	-14.62 (1.601)	
95% CI [2]	-9.81, -2.16	-10.07, -4.39	-14.19, -6.34	-17.79, -11.45	
Difference (95% CI) in CFB [2]		-1.24 (-5.47, 2.98)		-4.35 (-8.93, 0.22)	
p-value [3]		0.559		0.062	

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	24	47	44	84	
Mean (StdDev)	27.81 (10.625)	22.59 (10.214)	52.46 (19.517)	44.76 (19.928)	
Median	28.49	20.43	50.21	43.06	
Min, Max	7.3, 48.4	7.0, 43.5	12.5, 90.0	4.1, 92.2	
C4D1 CFB					
n	24	47	44	84	
LS Mean (StdErr) [2]	-5.20 (1.908)	-8.40 (1.394)	-11.52 (2.385)	-17.25 (1.891)	
95% CI [2]	-9.00, -1.39	-11.18, -5.62	-16.24, -6.80	-20.99, -13.51	
Difference (95% CI) in CFB [2]		-3.20 (-7.44, 1.04)		-5.73 (-11.15, -0.31)	
p-value [3]		0.136		0.039	

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	50	43	84	
Mean (StdDev)	26.85 (10.655)	22.84 (10.907)	52.58 (19.515)	42.85 (20.454)	
Median	28.93	19.89	52.46	40.69	
Min, Max	6.6, 41.6	6.9, 49.5	9.6, 90.0	1.3, 89.6	
C5D1 CFB					
n	23	50	43	84	
LS Mean (StdErr) [2]	-5.41 (2.105)	-8.14 (1.472)	-11.69 (2.587)	-19.30 (2.036)	
95% CI [2]	-9.61, -1.21	-11.07, -5.20	-16.81, -6.57	-23.33, -15.27	
Difference (95% CI) in CFB [2]		-2.73 (-7.38, 1.92)		-7.62 (-13.50, -1.74)	
p-value [3]		0.246		0.012	

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	24	49	40	82	
Mean (StdDev)	28.41 (12.052)	21.96 (10.834)	48.40 (19.798)	41.07 (21.241)	
Median	28.29	19.79	47.36	40.43	
Min, Max	5.3, 51.3	5.6, 56.1	10.2, 83.4	1.5, 100.6	
C6D1 CFB					
n	24	49	40	82	
LS Mean (StdErr) [2]	-4.16 (2.219)	-9.14 (1.641)	-14.73 (2.785)	-20.81 (2.152)	
95% CI [2]	-8.59, 0.26	-12.41, -5.87	-20.24, -9.22	-25.07, -16.55	
Difference (95% CI) in CFB [2]		-4.98 (-9.84, -0.11)		-6.08 (-12.44, 0.28)	
p-value [3]		0.045		0.061	

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	23	49	42	79	
Mean (StdDev)	28.04 (10.597)	22.12 (10.876)	50.14 (21.278)	40.30 (21.394)	
Median	27.54	21.08	51.75	40.23	
Min, Max	9.2, 45.1	6.4, 51.9	5.5, 86.1	0.9, 103.5	
C7D1 CFB					
n	23	49	42	79	
LS Mean (StdErr) [2]	-4.98 (2.218)	-9.15 (1.558)	-13.95 (2.849)	-21.75 (2.284)	
95% CI [2]	-9.40, -0.55	-12.25, -6.04	-19.59, -8.31	-26.27, -17.23	
Difference (95% CI) in CFB [2]		-4.17 (-9.09, 0.75)		-7.80 (-14.34, -1.27)	
Hedges'G (95% CI) in CFB		-0.38 (-0.90, 0.11)		-0.39 (-0.78, -0.02)	
p-value [3]		0.095		0.020	
					0.438

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	15	28	56	111	
Mean (StdDev)	54.75 (22.307)	51.22 (22.419)	51.81 (19.276)	49.90 (18.333)	
Median	52.50	46.35	46.73	48.71	
Min, Max	18.0, 92.4	12.1, 98.4	18.5, 104.4	18.9, 102.7	

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	25	55	108	
Mean (StdDev)	44.63 (20.453)	45.58 (23.837)	47.22 (19.501)	41.83 (18.061)	
Median	39.64	40.86	43.79	39.98	
Min, Max	14.8, 84.9	12.4, 89.6	12.9, 98.9	10.9, 92.3	
C2D1 CFB					
n	15	25	55	106	
LS Mean (StdErr) [2]	-9.15 (2.777)	-6.13 (2.070)	-4.36 (1.034)	-7.69 (0.760)	
95% CI [2]	-14.77, -3.52	-10.33, -1.94	-6.41, -2.32	-9.19, -6.19	
Difference (95% CI) in CFB [2]		3.01 (-3.91, 9.93)		-3.33 (-5.83, -0.83)	
p-value [3]		0.384		0.009	

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	27	56	107	
Mean (StdDev)	40.90 (20.335)	42.21 (22.975)	44.83 (19.975)	38.07 (18.451)	
Median	36.64	40.00	42.54	36.50	
Min, Max	13.9, 79.9	8.9, 86.6	6.5, 93.8	8.8, 91.9	
C3D1 CFB					
n	15	27	56	105	
LS Mean (StdErr) [2]	-12.82 (3.091)	-9.16 (2.237)	-6.20 (1.489)	-11.19 (1.106)	
95% CI [2]	-19.07, -6.57	-13.68, -4.63	-9.14, -3.26	-13.38, -9.01	
Difference (95% CI) in CFB [2]		3.66 (-3.89, 11.22)		-4.99 (-8.60, -1.38)	
p-value [3]		0.333		0.007	

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	14	27	54	106	
Mean (StdDev)	39.84 (20.171)	40.21 (22.384)	44.78 (20.767)	36.26 (19.507)	
Median	37.29	39.62	41.01	34.59	
Min, Max	14.5, 78.7	6.7, 92.0	7.3, 90.0	4.1, 92.2	
C4D1 CFB					
n	14	27	54	104	
LS Mean (StdErr) [2]	-13.29 (3.793)	-10.81 (2.674)	-6.59 (1.720)	-13.29 (1.265)	
95% CI [2]	-20.97, -5.62	-16.22, -5.39	-9.98, -3.19	-15.79, -10.79	
Difference (95% CI) in CFB [2]		2.49 (-6.73, 11.71)		-6.71 (-10.84, -2.57)	
p-value [3]		0.588		0.002	

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	28	52	108	
Mean (StdDev)	38.62 (17.937)	39.45 (21.139)	44.96 (21.596)	34.67 (19.661)	
Median	35.25	34.90	41.26	32.57	
Min, Max	14.9, 73.3	3.8, 84.6	6.6, 90.0	1.3, 89.6	
C5D1 CFB					
n	14	28	52	106	
LS Mean (StdErr) [2]	-14.02 (4.128)	-11.02 (2.847)	-6.47 (1.875)	-14.67 (1.334)	
95% CI [2]	-22.37, -5.67	-16.78, -5.26	-10.17, -2.76	-17.31, -12.04	
Difference (95% CI) in CFB [2]		3.00 (-7.00, 13.00)		-8.21 (-12.67, -3.74)	
p-value [3]		0.547		<0.001	

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	26	50	107	
Mean (StdDev)	36.86 (18.918)	39.56 (22.981)	42.04 (20.037)	32.71 (19.328)	
Median	34.21	32.37	39.68	31.08	
Min, Max	10.2, 72.5	4.1, 100.6	5.3, 83.4	1.5, 93.4	
C6D1 CFB					
n	14	26	50	105	
LS Mean (StdErr) [2]	-15.50 (4.682)	-11.73 (3.382)	-7.77 (1.931)	-15.95 (1.355)	
95% CI [2]	-24.98, -6.01	-18.58, -4.87	-11.59, -3.95	-18.62, -13.27	
Difference (95% CI) in CFB [2]		3.77 (-7.65, 15.19)		-8.18 (-12.78, -3.57)	
p-value [3]		0.508		<0.001	

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	14	27	51	103	
Mean (StdDev)	37.92 (18.325)	36.74 (22.994)	43.53 (21.719)	32.63 (19.246)	
Median	37.34	31.79	40.33	30.93	
Min, Max	5.5, 71.3	3.7, 103.5	9.2, 86.1	0.9, 93.6	
C7D1 CFB					
n	14	27	51	101	
LS Mean (StdErr) [2]	-14.60 (4.797)	-13.01 (3.358)	-7.55 (1.995)	-16.18 (1.437)	
95% CI [2]	-24.31, -4.89	-19.81, -6.22	-11.50, -3.61	-19.02, -13.34	
Difference (95% CI) in CFB [2]		1.58 (-10.14, 13.30)		-8.63 (-13.41, -3.85)	
Hedges'G (95% CI) in CFB		0.09 (-0.57, 0.76)		-0.60 (-0.95, -0.26)	
p-value [3]		0.786		<0.001	
					0.063

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	67	129	4	10	
Mean (StdDev)	52.51 (19.752)	49.61 (19.065)	51.13 (24.146)	57.34 (19.722)	
Median	47.79	46.50	43.50	59.16	
Min, Max	18.0, 104.4	12.1, 102.7	32.2, 85.3	22.5, 85.9	

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	66	123	4	10	
Mean (StdDev)	46.66 (19.951)	41.92 (18.861)	46.79 (14.127)	50.07 (23.118)	
Median	42.82	39.17	49.79	48.71	
Min, Max	12.9, 98.9	10.9, 92.3	27.4, 60.1	13.0, 80.6	
C2D1 CFB					
n	66	121	4	10	
LS Mean (StdErr) [2]	-5.70 (1.092)	-7.74 (0.875)	0.26 (7.762)	-3.03 (5.943)	
95% CI [2]	-7.86, -3.55	-9.47, -6.02	-17.04, 17.55	-16.28, 10.21	
Difference (95% CI) in CFB [2]		-2.04 (-4.50, 0.42)		-3.29 (-17.66, 11.07)	
p-value [3]		0.104		0.620	

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	67	124	4	10	
Mean (StdDev)	43.88 (20.294)	38.14 (19.024)	46.02 (15.474)	48.39 (22.837)	
Median	41.00	36.32	50.25	48.48	
Min, Max	6.5, 93.8	8.8, 91.9	24.2, 59.4	10.6, 78.1	
C3D1 CFB					
n	67	122	4	10	
LS Mean (StdErr) [2]	-7.81 (1.487)	-11.21 (1.176)	0.52 (9.302)	-4.01 (7.122)	
95% CI [2]	-10.75, -4.88	-13.53, -8.89	-20.20, 21.25	-19.88, 11.85	
Difference (95% CI) in CFB [2]		-3.40 (-6.75, -0.05)		-4.54 (-21.75, 12.67)	
p-value [3]		0.047		0.570	

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	64	123	4	10	
Mean (StdDev)	43.79 (21.120)	36.31 (19.729)	43.23 (10.227)	46.30 (23.355)	
Median	38.34	34.08	47.18	43.46	
Min, Max	7.3, 90.0	4.1, 92.2	28.1, 50.4	10.0, 78.4	
C4D1 CFB					
n	64	121	4	10	
LS Mean (StdErr) [2]	-8.25 (1.738)	-13.30 (1.349)	-1.42 (11.413)	-4.35 (8.738)	
95% CI [2]	-11.68, -4.83	-15.96, -10.64	-26.85, 24.01	-23.82, 15.12	
Difference (95% CI) in CFB [2]		-5.05 (-8.93, -1.17)		-2.92 (-24.04, 18.19)	
p-value [3]		0.011		0.764	

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	62	126	4	10	
Mean (StdDev)	43.86 (21.331)	34.57 (18.940)	39.88 (14.101)	49.32 (28.042)	
Median	40.00	32.68	43.61	48.68	
Min, Max	6.6, 90.0	1.3, 89.6	19.9, 52.5	7.1, 82.4	
C5D1 CFB					
n	62	124	4	10	
LS Mean (StdErr) [2]	-8.04 (1.799)	-14.66 (1.358)	2.24 (16.167)	3.24 (12.378)	
95% CI [2]	-11.59, -4.49	-17.34, -11.98	-33.78, 38.26	-24.34, 30.82	
Difference (95% CI) in CFB [2]		-6.62 (-10.63, -2.62)		1.00 (-28.92, 30.92)	
p-value [3]		0.001		0.942	

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	60	123	4	10	
Mean (StdDev)	40.82 (20.331)	33.24 (19.585)	42.16 (8.644)	44.03 (25.625)	
Median	38.63	31.17	45.25	41.71	
Min, Max	5.3, 83.4	1.5, 100.6	29.4, 48.7	5.6, 80.0	
C6D1 CFB					
n	60	121	4	10	
LS Mean (StdErr) [2]	-9.69 (1.990)	-15.60 (1.527)	4.95 (11.874)	-0.72 (9.091)	
95% CI [2]	-13.61, -5.76	-18.61, -12.58	-21.51, 31.41	-20.98, 19.54	
Difference (95% CI) in CFB [2]		-5.91 (-10.36, -1.46)		-5.67 (-27.64, 16.30)	
p-value [3]		0.010		0.578	

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	62	120	3	10	
Mean (StdDev)	42.14 (21.506)	32.74 (19.370)	46.14 (4.272)	42.42 (26.618)	
Median	37.75	30.64	44.79	36.68	
Min, Max	5.5, 86.1	0.9, 103.5	42.7, 50.9	6.4, 81.5	
C7D1 CFB					
n	62	118	3	10	
LS Mean (StdErr) [2]	-9.27 (2.018)	-15.97 (1.552)	3.72 (15.308)	-2.31 (10.708)	
95% CI [2]	-13.25, -5.29	-19.04, -12.91	-30.91, 38.35	-26.53, 21.91	
Difference (95% CI) in CFB [2]		-6.70 (-11.24, -2.17)		-6.03 (-34.60, 22.54)	
Hedges'G (95% CI) in CFB		-0.40 (-0.72, -0.10)		-0.17 (-1.66, 1.24)	
p-value [3]		0.004		0.644	
					0.734

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	67	129	
Mean (StdDev)	44.41 (20.945)	63.12 (19.595)	52.91 (19.816)	49.16 (18.816)	
Median	42.71	61.04	47.79	45.92	
Min, Max	21.2, 71.0	28.6, 95.5	18.0, 104.4	12.1, 102.7	

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	9	66	124	
Mean (StdDev)	40.80 (20.188)	55.76 (18.484)	47.02 (19.652)	41.57 (19.000)	
Median	37.36	58.29	43.36	39.29	
Min, Max	20.2, 68.3	28.1, 83.3	12.9, 98.9	10.9, 92.3	
C2D1 CFB					
n	4	9	66	122	
LS Mean (StdErr) [2]	-5.42 (2.494)	-9.60 (2.820)	-5.62 (1.141)	-7.57 (0.904)	
95% CI [2]	-11.07, 0.22	-15.98, -3.22	-7.87, -3.37	-9.36, -5.79	
Difference (95% CI) in CFB [2]		-4.18 (-11.47, 3.11)		-1.95 (-4.50, 0.59)	
p-value [3]		0.227		0.132	

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	8	67	126	
Mean (StdDev)	38.09 (19.773)	49.75 (16.996)	44.35 (20.074)	38.22 (19.424)	
Median	35.04	48.64	42.21	37.33	
Min, Max	18.1, 64.2	29.1, 80.5	6.5, 93.8	8.8, 91.9	
C3D1 CFB					
n	4	8	67	124	
LS Mean (StdErr) [2]	-6.74 (5.144)	-12.43 (5.144)	-7.75 (1.530)	-10.82 (1.204)	
95% CI [2]	-18.60, 5.12	-24.30, -0.57	-10.76, -4.73	-13.19, -8.44	
Difference (95% CI) in CFB [2]		-5.69 (-20.86, 9.48)		-3.07 (-6.48, 0.33)	
p-value [3]		0.412		0.077	

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	4	9	64	124	
Mean (StdDev)	35.72 (22.134)	42.98 (17.198)	44.26 (20.576)	36.63 (20.285)	
Median	29.96	42.93	39.14	34.13	
Min, Max	15.6, 67.3	19.6, 80.2	7.3, 90.0	4.1, 92.2	
C4D1 CFB					
n	4	9	64	122	
LS Mean (StdErr) [2]	-11.36 (6.713)	-21.49 (6.713)	-8.00 (1.771)	-12.40 (1.369)	
95% CI [2]	-26.54, 3.83	-36.68, -6.31	-11.49, -4.50	-15.10, -9.70	
Difference (95% CI) in CFB [2]		-10.14 (-29.50, 9.23)		-4.41 (-8.32, -0.50)	
p-value [3]		0.267		0.027	

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	9	62	127	
Mean (StdDev)	32.84 (22.010)	38.74 (16.914)	44.31 (20.829)	35.43 (20.227)	
Median	28.13	38.15	41.26	32.79	
Min, Max	11.5, 63.6	18.6, 78.3	6.6, 90.0	1.3, 89.6	
C5D1 CFB					
n	4	9	62	125	
LS Mean (StdErr) [2]	-16.01 (6.489)	-27.25 (6.489)	-7.70 (1.913)	-13.06 (1.440)	
95% CI [2]	-30.69, -1.33	-41.93, -12.57	-11.47, -3.92	-15.90, -10.22	
Difference (95% CI) in CFB [2]		-11.24 (-29.95, 7.48)		-5.36 (-9.58, -1.14)	
p-value [3]		0.207		0.013	

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	60	124	
Mean (StdDev)	31.23 (23.091)	36.69 (17.836)	41.55 (19.580)	33.86 (20.396)	
Median	25.32	38.71	38.89	31.19	
Min, Max	10.1, 64.2	14.8, 76.4	5.3, 83.4	1.5, 100.6	
C6D1 CFB					
n	4	9	60	122	
LS Mean (StdErr) [2]	-18.59 (7.734)	-31.26 (7.734)	-8.90 (2.001)	-14.09 (1.530)	
95% CI [2]	-36.08, -1.10	-48.75, -13.76	-12.85, -4.95	-17.11, -11.07	
Difference (95% CI) in CFB [2]		-12.67 (-34.97, 9.64)		-5.19 (-9.61, -0.76)	
p-value [3]		0.231		0.022	

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	9	61	121	
Mean (StdDev)	32.38 (21.015)	37.12 (18.683)	42.97 (21.036)	33.21 (20.201)	
Median	29.20	36.79	40.08	30.93	
Min, Max	10.3, 60.9	14.1, 78.6	5.5, 86.1	0.9, 103.5	
C7D1 CFB					
n	4	9	61	119	
LS Mean (StdErr) [2]	-17.00 (8.254)	-30.11 (8.254)	-8.63 (2.063)	-14.67 (1.571)	
95% CI [2]	-35.68, 1.67	-48.79, -11.44	-12.70, -4.56	-17.77, -11.57	
Difference (95% CI) in CFB [2]		-13.11 (-36.92, 10.70)		-6.04 (-10.63, -1.45)	
Hedges'G (95% CI) in CFB		-0.53 (-2.00, 0.69)		-0.36 (-0.68, -0.05)	
p-value [3]		0.244		0.010	
					0.605

Gastrointestinal Domain Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	130	11	9	
Mean (StdDev)	11.33 (6.771)	9.74 (6.156)	5.44 (5.041)	9.30 (7.222)	
Median	10.11	8.48	4.00	7.00	
Min, Max	0.1, 28.0	0.0, 26.8	0.0, 15.3	0.3, 18.9	

Gastrointestinal Domain Score					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	60	128	11	9	
Mean (StdDev)	9.25 (6.500)	8.06 (5.884)	4.21 (3.281)	7.39 (5.268)	
Median	7.89	6.92	3.50	5.93	
Min, Max	0.4, 26.4	0.0, 24.0	0.0, 9.8	1.6, 16.4	
C2D1 CFB					
n	60	126	11	9	
LS Mean (StdErr) [2]	-1.72 (0.399)	-1.48 (0.296)	-3.90 (1.243)	-4.79 (1.577)	
95% CI [2]	-2.50, -0.93	-2.06, -0.89	-6.54, -1.27	-8.13, -1.44	
Difference (95% CI) in CFB [2]		0.24 (-0.64, 1.12)		-0.88 (-3.34, 1.58)	
p-value [3]		0.590		0.458	

Gastrointestinal Domain Score					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	60	126	11	9	
Mean (StdDev)	8.41 (6.481)	7.28 (5.647)	4.61 (4.241)	5.48 (4.631)	
Median	7.24	6.45	3.43	4.79	
Min, Max	0.0, 23.9	0.0, 24.0	0.0, 12.1	0.4, 16.4	
C3D1 CFB					
n	60	124	11	9	
LS Mean (StdErr) [2]	-2.52 (0.509)	-2.24 (0.379)	-3.55 (1.904)	-6.51 (2.415)	
95% CI [2]	-3.52, -1.51	-2.99, -1.50	-7.58, 0.49	-11.63, -1.39	
Difference (95% CI) in CFB [2]		0.27 (-0.86, 1.40)		-2.97 (-6.73, 0.80)	
p-value [3]		0.634		0.114	

Gastrointestinal Domain Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	58	126	10	9	
Mean (StdDev)	8.57 (6.458)	6.67 (5.710)	4.79 (3.460)	4.88 (4.760)	
Median	7.63	5.59	6.07	4.07	
Min, Max	0.0, 23.5	0.0, 24.8	0.0, 9.6	0.2, 15.5	
C4D1 CFB					
n	58	124	10	9	
LS Mean (StdErr) [2]	-2.59 (0.592)	-2.94 (0.434)	-3.44 (2.036)	-6.92 (2.564)	
95% CI [2]	-3.76, -1.42	-3.79, -2.08	-7.78, 0.90	-12.39, -1.46	
Difference (95% CI) in CFB [2]		-0.35 (-1.65, 0.95)		-3.48 (-7.55, 0.59)	
p-value [3]		0.596		0.088	

Gastrointestinal Domain Score					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	58	128	9	9	
Mean (StdDev)	8.56 (6.154)	6.54 (5.833)	5.38 (3.880)	3.96 (4.811)	
Median	7.52	5.50	6.43	2.54	
Min, Max	0.0, 23.3	0.0, 25.0	0.0, 10.4	0.1, 15.6	
C5D1 CFB					
n	58	126	9	9	
LS Mean (StdErr) [2]	-2.55 (0.630)	-3.06 (0.455)	-3.37 (2.476)	-8.27 (3.088)	
95% CI [2]	-3.79, -1.30	-3.96, -2.16	-8.68, 1.94	-14.89, -1.65	
Difference (95% CI) in CFB [2]		-0.52 (-1.90, 0.87)		-4.90 (-9.91, 0.11)	
p-value [3]		0.462		0.054	

Gastrointestinal Domain Score					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	56	127	10	9	
Mean (StdDev)	7.68 (6.132)	5.97 (5.610)	3.84 (2.936)	4.48 (5.031)	
Median	5.96	4.50	3.54	3.46	
Min, Max	0.1, 20.8	0.0, 25.5	0.0, 8.1	0.4, 16.1	
C6D1 CFB					
n	56	125	10	9	
LS Mean (StdErr) [2]	-3.07 (0.640)	-3.46 (0.457)	-4.10 (2.133)	-6.82 (2.686)	
95% CI [2]	-4.33, -1.80	-4.36, -2.56	-8.65, 0.44	-12.54, -1.09	
Difference (95% CI) in CFB [2]		-0.40 (-1.81, 1.01)		-2.71 (-6.97, 1.55)	
p-value [3]		0.580		0.195	

Gastrointestinal Domain Score					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	56	124	10	9	
Mean (StdDev)	7.90 (6.417)	6.04 (5.579)	4.42 (4.199)	4.20 (4.867)	
Median	6.00	4.76	4.00	3.21	
Min, Max	0.1, 22.9	0.0, 26.4	0.0, 11.1	0.0, 15.5	
C7D1 CFB					
n	56	122	10	9	
LS Mean (StdErr) [2]	-2.91 (0.671)	-3.33 (0.484)	-4.50 (2.134)	-8.73 (2.687)	
95% CI [2]	-4.23, -1.58	-4.28, -2.38	-9.05, 0.05	-14.46, -3.01	
Difference (95% CI) in CFB [2]		-0.42 (-1.90, 1.06)		-4.23 (-8.49, 0.03)	
Hedges'G (95% CI) in CFB		-0.08 (-0.40, 0.24)		-0.55 (-1.61, 0.37)	
p-value [3]		0.573		0.051	
					0.230

Skin Domain Score					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	130	11	9	
Mean (StdDev)	16.58 (7.546)	15.31 (7.102)	20.54 (7.420)	18.18 (7.309)	
Median	17.79	14.85	20.71	22.00	
Min, Max	0.0, 30.0	0.0, 30.0	8.1, 30.0	6.6, 26.9	

Skin Domain Score					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	60	128	11	9	
Mean (StdDev)	15.08 (7.105)	12.96 (6.362)	18.67 (8.923)	12.46 (7.254)	
Median	16.25	12.78	18.86	11.29	
Min, Max	0.0, 29.2	0.0, 28.5	5.6, 29.8	4.6, 25.9	
C2D1 CFB					
n	60	126	11	9	
LS Mean (StdErr) [2]	-1.41 (0.460)	-2.47 (0.342)	-1.35 (2.654)	-6.01 (3.366)	
95% CI [2]	-2.31, -0.50	-3.15, -1.80	-6.98, 4.28	-13.14, 1.13	
Difference (95% CI) in CFB [2]		-1.07 (-2.09, -0.05)		-4.66 (-9.90, 0.59)	
p-value [3]		0.039		0.078	

Skin Domain Score					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	60	126	11	9	
Mean (StdDev)	14.60 (7.438)	11.50 (6.188)	17.88 (8.604)	10.86 (7.921)	
Median	15.01	10.71	21.00	9.21	
Min, Max	0.0, 29.4	0.0, 28.1	6.0, 28.6	2.4, 24.1	
C3D1 CFB					
n	60	124	11	9	
LS Mean (StdErr) [2]	-1.54 (0.592)	-3.67 (0.440)	-2.50 (3.003)	-7.90 (3.808)	
95% CI [2]	-2.71, -0.37	-4.54, -2.81	-8.86, 3.87	-15.97, 0.17	
Difference (95% CI) in CFB [2]		-2.14 (-3.45, -0.82)		-5.40 (-11.34, 0.53)	
p-value [3]		0.002		0.072	

Skin Domain Score					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	58	126	10	9	
Mean (StdDev)	14.32 (7.491)	10.89 (6.254)	18.24 (8.738)	9.81 (8.514)	
Median	14.92	10.29	21.00	6.23	
Min, Max	0.0, 29.7	0.0, 28.6	6.9, 28.6	1.7, 24.0	
C4D1 CFB					
n	58	124	10	9	
LS Mean (StdErr) [2]	-1.83 (0.652)	-4.29 (0.477)	-1.96 (3.668)	-7.97 (4.619)	
95% CI [2]	-3.11, -0.54	-5.23, -3.35	-9.78, 5.86	-17.82, 1.87	
Difference (95% CI) in CFB [2]		-2.46 (-3.89, -1.03)		-6.01 (-13.34, 1.31)	
p-value [3]		<0.001		0.101	

Skin Domain Score					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	58	128	9	9	
Mean (StdDev)	13.94 (7.588)	10.39 (6.022)	20.71 (7.229)	8.61 (8.623)	
Median	15.03	9.71	22.36	5.57	
Min, Max	0.0, 29.9	0.1, 28.5	9.8, 30.0	0.3, 23.2	
C5D1 CFB					
n	58	126	9	9	
LS Mean (StdErr) [2]	-2.26 (0.712)	-4.80 (0.514)	-0.93 (3.585)	-9.95 (4.471)	
95% CI [2]	-3.67, -0.86	-5.81, -3.78	-8.62, 6.76	-19.54, -0.36	
Difference (95% CI) in CFB [2]		-2.54 (-4.10, -0.97)		-9.03 (-16.28, -1.78)	
p-value [3]		0.002		0.018	

Skin Domain Score					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	56	127	10	9	
Mean (StdDev)	14.04 (7.356)	10.03 (6.216)	18.69 (9.169)	8.44 (8.189)	
Median	14.80	9.57	21.29	7.14	
Min, Max	0.0, 29.8	0.0, 30.0	1.6, 30.0	0.9, 22.9	
C6D1 CFB					
n	56	125	10	9	
LS Mean (StdErr) [2]	-2.08 (0.787)	-5.07 (0.563)	-1.88 (3.511)	-9.83 (4.420)	
95% CI [2]	-3.63, -0.52	-6.18, -3.96	-9.36, 5.60	-19.25, -0.40	
Difference (95% CI) in CFB [2]		-2.99 (-4.72, -1.25)		-7.94 (-14.96, -0.93)	
p-value [3]		<0.001		0.029	

Skin Domain Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	56	124	10	9	
Mean (StdDev)	14.25 (7.090)	9.71 (6.219)	19.05 (8.333)	9.70 (8.528)	
Median	14.65	8.00	21.77	8.36	
Min, Max	1.2, 30.0	0.0, 30.0	5.9, 29.9	0.0, 22.6	
C7D1 CFB					
n	56	122	10	9	
LS Mean (StdErr) [2]	-2.12 (0.813)	-5.29 (0.586)	-1.02 (3.129)	-7.05 (3.940)	
95% CI [2]	-3.73, -0.52	-6.45, -4.14	-7.69, 5.65	-15.44, 1.35	
Difference (95% CI) in CFB [2]		-3.17 (-4.96, -1.37)		-6.03 (-12.27, 0.22)	
Hedges'G (95% CI) in CFB		-0.50 (-0.83, -0.18)		-0.53 (-1.59, 0.38)	
p-value [3]		<0.001		0.058	
					0.315

Neurocognitive Symptom Cluster

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	130	11	9	
Mean (StdDev)	13.71 (7.068)	13.23 (6.752)	7.26 (2.552)	10.28 (6.954)	
Median	12.89	12.81	7.69	10.92	
Min, Max	0.4, 29.1	0.5, 29.6	2.2, 11.3	0.0, 20.6	

Neurocognitive Symptom Cluster

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	60	128	11	9	
Mean (StdDev)	12.29 (6.887)	11.49 (6.663)	6.71 (2.866)	8.59 (6.531)	
Median	10.49	10.25	6.79	11.00	
Min, Max	0.2, 27.4	1.1, 30.0	1.2, 11.4	0.0, 18.9	
C2D1 CFB					
n	60	126	11	9	
LS Mean (StdErr) [2]	-1.25 (0.426)	-1.76 (0.317)	0.04 (1.283)	-1.34 (1.627)	
95% CI [2]	-2.09, -0.41	-2.39, -1.14	-2.68, 2.76	-4.79, 2.11	
Difference (95% CI) in CFB [2]		-0.51 (-1.45, 0.43)		-1.38 (-3.92, 1.16)	
p-value [3]		0.287		0.265	

Neurocognitive Symptom Cluster

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	60	126	11	9	
Mean (StdDev)	11.30 (6.742)	10.50 (6.597)	6.04 (3.515)	7.82 (6.761)	
Median	9.96	9.11	4.93	8.93	
Min, Max	0.1, 27.3	0.1, 30.0	0.3, 11.9	0.0, 19.2	
C3D1 CFB					
n	60	124	11	9	
LS Mean (StdErr) [2]	-2.09 (0.523)	-2.67 (0.390)	-1.19 (1.946)	-3.21 (2.468)	
95% CI [2]	-3.13, -1.06	-3.44, -1.91	-5.31, 2.94	-8.44, 2.02	
Difference (95% CI) in CFB [2]		-0.58 (-1.74, 0.58)		-2.02 (-5.87, 1.82)	
p-value [3]		0.324		0.281	

Neurocognitive Symptom Cluster

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	58	126	10	9	
Mean (StdDev)	11.17 (6.755)	10.03 (6.718)	6.40 (3.987)	7.34 (6.660)	
Median	9.96	8.56	5.89	7.57	
Min, Max	0.1, 25.6	0.0, 29.9	0.0, 11.6	0.2, 18.9	
C4D1 CFB					
n	58	124	10	9	
LS Mean (StdErr) [2]	-2.32 (0.623)	-3.24 (0.456)	-0.63 (2.135)	-3.16 (2.689)	
95% CI [2]	-3.55, -1.09	-4.14, -2.34	-5.18, 3.92	-8.89, 2.57	
Difference (95% CI) in CFB [2]		-0.92 (-2.29, 0.45)		-2.53 (-6.80, 1.73)	
p-value [3]		0.189		0.225	

Neurocognitive Symptom Cluster

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	58	128	9	9	
Mean (StdDev)	10.84 (6.911)	9.87 (6.618)	6.50 (3.848)	5.88 (6.374)	
Median	9.96	8.15	5.29	5.71	
Min, Max	0.0, 26.2	0.0, 30.0	0.1, 12.5	0.0, 20.3	
C5D1 CFB					
n	58	126	9	9	
LS Mean (StdErr) [2]	-2.53 (0.641)	-3.27 (0.463)	-0.46 (2.064)	-4.46 (2.574)	
95% CI [2]	-3.79, -1.27	-4.18, -2.35	-4.89, 3.96	-9.98, 1.06	
Difference (95% CI) in CFB [2]		-0.74 (-2.14, 0.67)		-4.00 (-8.17, 0.18)	
p-value [3]		0.303		0.059	

Neurocognitive Symptom Cluster

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	56	127	10	9	
Mean (StdDev)	10.40 (6.628)	9.20 (6.666)	6.45 (3.696)	5.91 (6.534)	
Median	9.00	7.57	6.00	5.79	
Min, Max	0.0, 25.0	0.1, 30.0	0.0, 12.0	0.0, 20.4	
C6D1 CFB					
n	56	125	10	9	
LS Mean (StdErr) [2]	-2.83 (0.673)	-3.87 (0.481)	-0.46 (1.968)	-4.43 (2.478)	
95% CI [2]	-4.16, -1.50	-4.82, -2.92	-4.66, 3.73	-9.71, 0.85	
Difference (95% CI) in CFB [2]		-1.04 (-2.52, 0.44)		-3.97 (-7.90, -0.04)	
p-value [3]		0.168		0.048	

Neurocognitive Symptom Cluster					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	56	124	10	9	
Mean (StdDev)	10.44 (6.862)	9.15 (6.672)	7.14 (3.954)	5.54 (6.469)	
Median	9.18	8.28	7.37	3.43	
Min, Max	0.0, 23.4	0.0, 30.0	0.0, 12.9	0.0, 19.9	
C7D1 CFB					
n	56	122	10	9	
LS Mean (StdErr) [2]	-2.85 (0.686)	-3.83 (0.494)	-0.55 (2.126)	-5.89 (2.677)	
95% CI [2]	-4.20, -1.49	-4.81, -2.86	-5.08, 3.98	-11.59, -0.18	
Difference (95% CI) in CFB [2]		-0.99 (-2.50, 0.53)		-5.34 (-9.58, -1.09)	
Hedges'G (95% CI) in CFB		-0.18 (-0.50, 0.13)		-0.69 (-1.79, 0.21)	
p-value [3]		0.199		0.017	
					0.184

Gastrointestinal Domain Score					
	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	17	41	54	98	
Mean (StdDev)	11.30 (7.549)	9.24 (5.754)	10.14 (6.662)	9.91 (6.398)	
Median	10.93	9.07	9.74	8.41	
Min, Max	0.0, 23.8	0.3, 26.8	0.1, 28.0	0.0, 26.3	

Gastrointestinal Domain Score					
	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	17	40	54	97	
Mean (StdDev)	9.37 (5.680)	7.76 (5.372)	8.19 (6.592)	8.12 (6.033)	
Median	8.42	7.11	7.11	6.79	
Min, Max	0.0, 20.4	0.2, 21.4	0.4, 26.4	0.0, 24.0	
C2D1 CFB					
n	17	40	54	95	
LS Mean (StdErr) [2]	-1.82 (0.753)	-1.30 (0.518)	-1.65 (0.430)	-1.64 (0.360)	
95% CI [2]	-3.33, -0.31	-2.33, -0.26	-2.50, -0.80	-2.35, -0.93	
Difference (95% CI) in CFB [2]		0.52 (-1.18, 2.23)		0.01 (-0.94, 0.95)	
p-value [3]		0.541		0.986	

Gastrointestinal Domain Score					
	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	40	54	95	
Mean (StdDev)	7.63 (6.054)	7.61 (4.891)	7.88 (6.450)	6.97 (5.871)	
Median	7.15	7.59	6.74	5.21	
Min, Max	0.0, 22.0	0.2, 22.2	0.1, 23.9	0.0, 24.0	
C3D1 CFB					
n	17	40	54	93	
LS Mean (StdErr) [2]	-3.35 (0.915)	-1.28 (0.630)	-2.12 (0.554)	-2.92 (0.464)	
95% CI [2]	-5.19, -1.52	-2.55, -0.02	-3.22, -1.03	-3.84, -2.00	
Difference (95% CI) in CFB [2]		2.07 (-0.01, 4.15)		-0.80 (-2.02, 0.43)	
p-value [3]		0.051		0.200	

Gastrointestinal Domain Score					
	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	17	40	51	95	
Mean (StdDev)	7.65 (6.506)	6.58 (4.978)	8.14 (6.208)	6.54 (5.941)	
Median	6.93	5.73	6.86	5.36	
Min, Max	0.0, 21.4	0.0, 20.3	0.0, 23.5	0.0, 24.8	
C4D1 CFB					
n	17	40	51	93	
LS Mean (StdErr) [2]	-3.47 (1.053)	-2.44 (0.724)	-2.07 (0.654)	-3.33 (0.534)	
95% CI [2]	-5.58, -1.36	-3.89, -0.99	-3.36, -0.77	-4.39, -2.28	
Difference (95% CI) in CFB [2]		1.03 (-1.36, 3.42)		-1.27 (-2.69, 0.15)	
p-value [3]		0.392		0.080	

Gastrointestinal Domain Score					
	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	40	50	97	
Mean (StdDev)	8.04 (5.912)	6.06 (4.218)	8.17 (6.059)	6.49 (6.343)	
Median	7.86	6.04	7.18	4.64	
Min, Max	0.0, 20.2	0.0, 15.5	0.0, 23.3	0.0, 25.0	
C5D1 CFB					
n	17	40	50	95	
LS Mean (StdErr) [2]	-2.91 (0.969)	-2.81 (0.667)	-2.16 (0.749)	-3.44 (0.592)	
95% CI [2]	-4.85, -0.96	-4.15, -1.47	-3.64, -0.68	-4.61, -2.27	
Difference (95% CI) in CFB [2]		0.09 (-2.11, 2.29)		-1.29 (-2.91, 0.34)	
p-value [3]		0.932		0.120	

Gastrointestinal Domain Score					
	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	17	40	49	96	
Mean (StdDev)	7.18 (6.107)	5.88 (4.480)	7.07 (5.905)	5.87 (5.986)	
Median	7.25	5.47	4.85	4.04	
Min, Max	0.0, 20.8	0.0, 18.0	0.2, 20.4	0.0, 25.5	
C6D1 CFB					
n	17	40	49	94	
LS Mean (StdErr) [2]	-3.87 (1.127)	-3.13 (0.776)	-2.65 (0.700)	-3.73 (0.555)	
95% CI [2]	-6.13, -1.61	-4.69, -1.58	-4.03, -1.26	-4.83, -2.64	
Difference (95% CI) in CFB [2]		0.74 (-1.83, 3.30)		-1.08 (-2.61, 0.44)	
p-value [3]		0.567		0.163	

Gastrointestinal Domain Score					
	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	17	40	49	93	
Mean (StdDev)	7.56 (6.518)	5.92 (4.479)	7.31 (6.202)	5.92 (5.957)	
Median	5.86	4.89	6.00	4.18	
Min, Max	0.0, 22.5	0.0, 17.7	0.1, 22.9	0.0, 26.4	
C7D1 CFB					
n	17	40	49	91	
LS Mean (StdErr) [2]	-3.49 (1.154)	-3.05 (0.794)	-2.54 (0.746)	-3.70 (0.595)	
95% CI [2]	-5.80, -1.17	-4.64, -1.45	-4.01, -1.06	-4.88, -2.52	
Difference (95% CI) in CFB [2]		0.44 (-2.18, 3.06)		-1.16 (-2.79, 0.47)	
Hedges'G (95% CI) in CFB		0.09 (-0.49, 0.67)		-0.21 (-0.56, 0.14)	
p-value [3]		0.738		0.161	
					0.301

Skin Domain Score					
	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	17	41	54	98	
Mean (StdDev)	17.74 (7.100)	13.85 (6.750)	17.02 (7.823)	16.19 (7.195)	
Median	19.64	12.85	17.79	16.68	
Min, Max	2.5, 30.0	1.9, 30.0	0.0, 30.0	0.0, 30.0	

Skin Domain Score	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	17	40	54	97	
Mean (StdDev)	15.32 (6.828)	12.08 (5.995)	15.74 (7.705)	13.27 (6.553)	
Median	16.36	11.46	16.26	13.21	
Min, Max	2.1, 29.2	1.0, 26.8	0.0, 29.8	0.0, 28.5	
C2D1 CFB					
n	17	40	54	95	
LS Mean (StdErr) [2]	-2.66 (0.934)	-2.09 (0.642)	-1.06 (0.533)	-2.79 (0.446)	
95% CI [2]	-4.53, -0.79	-3.37, -0.80	-2.12, -0.01	-3.67, -1.91	
Difference (95% CI) in CFB [2]		0.58 (-1.54, 2.70)		-1.73 (-2.90, -0.56)	
p-value [3]		0.588		0.004	

Skin Domain Score	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	40	54	95	
Mean (StdDev)	14.95 (8.278)	10.49 (5.785)	15.15 (7.534)	11.87 (6.470)	
Median	16.29	9.81	14.64	11.36	
Min, Max	1.8, 28.9	2.3, 24.1	0.0, 29.4	0.0, 28.1	
C3D1 CFB					
n	17	40	54	93	
LS Mean (StdErr) [2]	-2.69 (1.120)	-3.36 (0.770)	-1.32 (0.680)	-3.90 (0.570)	
95% CI [2]	-4.94, -0.44	-4.91, -1.82	-2.66, 0.03	-5.02, -2.77	
Difference (95% CI) in CFB [2]		-0.67 (-3.21, 1.87)		-2.58 (-4.08, -1.08)	
p-value [3]		0.599		<0.001	

Skin Domain Score	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	17	40	51	95	
Mean (StdDev)	14.25 (7.804)	10.00 (6.011)	15.12 (7.788)	11.16 (6.550)	
Median	14.50	8.42	16.14	10.71	
Min, Max	1.8, 29.7	1.8, 24.5	0.0, 29.6	0.0, 28.6	
C4D1 CFB					
n	17	40	51	93	
LS Mean (StdErr) [2]	-3.19 (1.274)	-3.67 (0.876)	-1.38 (0.749)	-4.71 (0.611)	
95% CI [2]	-5.74, -0.63	-5.43, -1.91	-2.86, 0.10	-5.92, -3.50	
Difference (95% CI) in CFB [2]		-0.48 (-3.38, 2.41)		-3.33 (-4.96, -1.70)	
p-value [3]		0.740		<0.0001	

Skin Domain Score	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	40	50	97	
Mean (StdDev)	14.51 (8.164)	9.66 (5.799)	14.96 (7.809)	10.53 (6.370)	
Median	15.92	8.03	15.41	9.70	
Min, Max	1.4, 29.9	1.9, 25.2	0.0, 30.0	0.1, 28.5	
C5D1 CFB					
n	17	40	50	95	
LS Mean (StdErr) [2]	-2.90 (1.325)	-3.97 (0.911)	-1.57 (0.814)	-5.33 (0.644)	
95% CI [2]	-5.56, -0.24	-5.80, -2.15	-3.18, 0.04	-6.60, -4.06	
Difference (95% CI) in CFB [2]		-1.07 (-4.08, 1.94)		-3.76 (-5.52, -1.99)	
p-value [3]		0.478		<0.0001	

Skin Domain Score	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	17	40	49	96	
Mean (StdDev)	14.91 (7.693)	9.36 (5.065)	14.68 (7.865)	10.16 (6.811)	
Median	15.67	7.54	14.36	9.21	
Min, Max	1.4, 29.6	1.1, 23.1	0.0, 30.0	0.0, 30.0	
C6D1 CFB					
n	17	40	49	94	
LS Mean (StdErr) [2]	-2.53 (1.311)	-4.36 (0.903)	-1.82 (0.919)	-5.55 (0.729)	
95% CI [2]	-5.16, 0.10	-6.17, -2.55	-3.64, -0.01	-6.99, -4.11	
Difference (95% CI) in CFB [2]		-1.83 (-4.81, 1.15)		-3.73 (-5.74, -1.72)	
p-value [3]		0.224		<0.001	

Skin Domain Score	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	17	40	49	93	
Mean (StdDev)	15.17 (7.885)	9.55 (5.126)	14.91 (7.344)	9.78 (6.846)	
Median	16.69	7.89	14.67	8.00	
Min, Max	1.4, 30.0	2.3, 22.8	1.2, 30.0	0.0, 30.0	
C7D1 CFB					
n	17	40	49	91	
LS Mean (StdErr) [2]	-2.34 (1.306)	-4.24 (0.899)	-1.92 (0.931)	-5.89 (0.744)	
95% CI [2]	-4.96, 0.28	-6.04, -2.44	-3.76, -0.07	-7.36, -4.42	
Difference (95% CI) in CFB [2]		-1.90 (-4.86, 1.07)		-3.98 (-6.01, -1.94)	
Hedges'G (95% CI) in CFB		-0.33 (-0.93, 0.24)		-0.57 (-0.94, -0.23)	
p-value [3]		0.206		<0.001	
					0.287

Neurocognitive Symptom Cluster

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	17	41	54	98	
Mean (StdDev)	13.20 (7.832)	10.56 (6.274)	12.55 (6.747)	14.07 (6.742)	
Median	11.00	8.79	11.82	13.96	
Min, Max	3.0, 23.6	0.0, 26.6	0.4, 29.1	0.5, 29.6	

Neurocognitive Symptom Cluster

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	17	40	54	97	
Mean (StdDev)	11.78 (6.842)	9.76 (6.130)	11.32 (6.756)	11.93 (6.810)	
Median	10.57	8.11	9.50	11.00	
Min, Max	1.8, 22.5	0.0, 25.1	0.2, 27.4	0.0, 30.0	
C2D1 CFB					
n	17	40	54	95	
LS Mean (StdErr) [2]	-1.75 (0.600)	-1.23 (0.413)	-1.05 (0.486)	-2.03 (0.407)	
95% CI [2]	-2.95, -0.55	-2.06, -0.41	-2.01, -0.09	-2.83, -1.22	
Difference (95% CI) in CFB [2]		0.51 (-0.85, 1.88)		-0.98 (-2.05, 0.09)	
p-value [3]		0.452		0.072	

Neurocognitive Symptom Cluster

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	40	54	95	
Mean (StdDev)	10.24 (7.040)	8.99 (5.374)	10.56 (6.542)	10.88 (7.025)	
Median	7.14	8.17	9.11	9.86	
Min, Max	1.1, 22.9	0.0, 23.3	0.1, 27.3	0.0, 30.0	
C3D1 CFB					
n	17	40	54	93	
LS Mean (StdErr) [2]	-3.36 (0.694)	-2.11 (0.477)	-1.70 (0.616)	-3.01 (0.516)	
95% CI [2]	-4.75, -1.96	-3.06, -1.15	-2.92, -0.48	-4.03, -1.99	
Difference (95% CI) in CFB [2]		1.25 (-0.33, 2.83)		-1.31 (-2.67, 0.04)	
p-value [3]		0.117		0.058	

Neurocognitive Symptom Cluster

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	17	40	51	95	
Mean (StdDev)	10.39 (7.510)	8.85 (5.676)	10.49 (6.380)	10.28 (7.104)	
Median	7.86	7.86	9.71	9.08	
Min, Max	1.0, 25.1	0.8, 24.1	0.0, 25.6	0.0, 29.9	
C4D1 CFB					
n	17	40	51	93	
LS Mean (StdErr) [2]	-3.19 (0.796)	-2.23 (0.548)	-1.98 (0.741)	-3.80 (0.604)	
95% CI [2]	-4.79, -1.60	-3.33, -1.13	-3.44, -0.51	-4.99, -2.60	
Difference (95% CI) in CFB [2]		0.96 (-0.85, 2.77)		-1.82 (-3.43, -0.21)	
p-value [3]		0.291		0.027	

Neurocognitive Symptom Cluster

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	40	50	97	
Mean (StdDev)	10.14 (7.542)	8.21 (5.790)	10.30 (6.511)	10.18 (6.925)	
Median	10.00	7.14	9.21	8.92	
Min, Max	1.1, 23.2	0.0, 22.8	0.0, 26.2	0.0, 30.0	
C5D1 CFB					
n	17	40	50	95	
LS Mean (StdErr) [2]	-3.09 (0.788)	-2.55 (0.542)	-2.16 (0.776)	-3.76 (0.614)	
95% CI [2]	-4.67, -1.51	-3.64, -1.46	-3.70, -0.63	-4.97, -2.55	
Difference (95% CI) in CFB [2]		0.54 (-1.24, 2.33)		-1.60 (-3.28, 0.08)	
p-value [3]		0.544		0.063	

Neurocognitive Symptom Cluster					
	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	17	40	49	96	
Mean (StdDev)	9.78 (7.232)	7.91 (5.482)	9.81 (6.183)	9.43 (7.104)	
Median	7.14	6.32	8.64	7.88	
Min, Max	1.0, 22.3	0.0, 22.4	0.0, 25.0	0.0, 30.0	
C6D1 CFB					
n	17	40	49	94	
LS Mean (StdErr) [2]	-3.79 (0.843)	-3.05 (0.581)	-2.29 (0.798)	-4.35 (0.633)	
95% CI [2]	-5.48, -2.10	-4.22, -1.89	-3.87, -0.71	-5.60, -3.09	
Difference (95% CI) in CFB [2]		0.74 (-1.18, 2.65)		-2.06 (-3.80, -0.31)	
p-value [3]		0.443		0.021	

Neurocognitive Symptom Cluster					
	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	17	40	49	93	
Mean (StdDev)	9.95 (7.139)	8.02 (5.666)	9.93 (6.467)	9.29 (7.088)	
Median	10.33	6.50	7.73	8.58	
Min, Max	2.4, 23.2	0.0, 22.5	0.0, 23.4	0.0, 30.0	
C7D1 CFB					
n	17	40	49	91	
LS Mean (StdErr) [2]	-3.60 (0.840)	-3.05 (0.578)	-2.23 (0.828)	-4.33 (0.661)	
95% CI [2]	-5.28, -1.92	-4.21, -1.90	-3.86, -0.59	-5.63, -3.02	
Difference (95% CI) in CFB [2]		0.55 (-1.36, 2.45)		-2.10 (-3.90, -0.29)	
Hedges'G (95% CI) in CFB		0.15 (-0.43, 0.74)		-0.34 (-0.70, 0.01)	
p-value [3]		0.569		0.023	
					0.097

Gastrointestinal Domain Score					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	33	58	38	81	
Mean (StdDev)	10.01 (7.107)	10.44 (6.769)	10.77 (6.688)	9.19 (5.748)	
Median	9.18	8.75	10.25	8.43	
Min, Max	0.0, 28.0	0.3, 26.8	0.1, 23.8	0.0, 24.0	

Gastrointestinal Domain Score					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	33	59	38	78	
Mean (StdDev)	8.16 (6.745)	8.86 (5.778)	8.74 (6.097)	7.38 (5.826)	
Median	6.75	7.60	7.75	5.75	
Min, Max	0.0, 26.4	0.5, 24.0	0.4, 21.9	0.0, 21.4	
C2D1 CFB					
n	33	57	38	78	
LS Mean (StdErr) [2]	-1.94 (0.509)	-1.89 (0.425)	-1.50 (0.516)	-1.30 (0.386)	
95% CI [2]	-2.95, -0.92	-2.73, -1.04	-2.52, -0.48	-2.06, -0.53	
Difference (95% CI) in CFB [2]		0.05 (-1.11, 1.20)		0.21 (-0.93, 1.34)	
p-value [3]		0.936		0.719	

Gastrointestinal Domain Score					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	33	58	38	77	
Mean (StdDev)	7.99 (6.762)	8.02 (5.563)	7.67 (5.989)	6.51 (5.555)	
Median	6.31	7.56	7.56	5.07	
Min, Max	0.0, 23.9	0.2, 24.0	0.0, 21.6	0.0, 22.2	
C3D1 CFB					
n	33	56	38	77	
LS Mean (StdErr) [2]	-2.15 (0.754)	-2.82 (0.632)	-2.52 (0.599)	-2.04 (0.449)	
95% CI [2]	-3.64, -0.65	-4.07, -1.56	-3.71, -1.33	-2.93, -1.15	
Difference (95% CI) in CFB [2]		-0.67 (-2.39, 1.05)		0.48 (-0.84, 1.80)	
p-value [3]		0.440		0.474	

Gastrointestinal Domain Score					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	31	58	37	77	
Mean (StdDev)	7.82 (6.523)	7.33 (5.870)	8.18 (6.075)	5.97 (5.452)	
Median	6.71	6.36	7.57	4.92	
Min, Max	0.0, 23.5	0.0, 24.8	0.0, 19.8	0.0, 24.1	
C4D1 CFB					
n	31	56	37	77	
LS Mean (StdErr) [2]	-2.63 (0.917)	-3.57 (0.742)	-2.28 (0.666)	-2.73 (0.495)	
95% CI [2]	-4.46, -0.81	-5.04, -2.09	-3.60, -0.96	-3.71, -1.75	
Difference (95% CI) in CFB [2]		-0.93 (-2.98, 1.11)		-0.45 (-1.92, 1.02)	
p-value [3]		0.366		0.543	

Gastrointestinal Domain Score					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	30	59	37	78	
Mean (StdDev)	8.09 (6.684)	7.02 (5.943)	8.18 (5.432)	5.87 (5.663)	
Median	7.46	6.29	7.21	4.00	
Min, Max	0.0, 23.3	0.0, 24.4	0.0, 19.9	0.0, 25.0	
C5D1 CFB					
n	30	57	37	78	
LS Mean (StdErr) [2]	-2.47 (0.955)	-3.83 (0.746)	-2.17 (0.761)	-2.77 (0.563)	
95% CI [2]	-4.37, -0.57	-5.31, -2.34	-3.68, -0.66	-3.89, -1.66	
Difference (95% CI) in CFB [2]		-1.36 (-3.49, 0.78)		-0.61 (-2.28, 1.07)	
p-value [3]		0.210		0.474	

Gastrointestinal Domain Score					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	29	58	37	78	
Mean (StdDev)	6.64 (6.303)	6.28 (5.765)	7.45 (5.646)	5.57 (5.436)	
Median	4.67	5.36	7.07	4.07	
Min, Max	0.0, 20.8	0.0, 25.5	0.1, 18.9	0.0, 22.7	
C6D1 CFB					
n	29	56	37	78	
LS Mean (StdErr) [2]	-3.29 (0.987)	-4.41 (0.769)	-2.78 (0.699)	-2.98 (0.515)	
95% CI [2]	-5.25, -1.32	-5.94, -2.88	-4.16, -1.39	-4.00, -1.96	
Difference (95% CI) in CFB [2]		-1.12 (-3.34, 1.09)		-0.21 (-1.75, 1.33)	
p-value [3]		0.316		0.789	

Gastrointestinal Domain Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	30	57	36	76	
Mean (StdDev)	7.10 (6.942)	6.04 (5.370)	7.60 (5.670)	5.83 (5.692)	
Median	5.36	5.43	6.49	4.07	
Min, Max	0.0, 22.9	0.0, 24.9	0.2, 19.3	0.0, 26.4	
C7D1 CFB					
n	30	55	36	76	
LS Mean (StdErr) [2]	-3.06 (1.030)	-4.49 (0.827)	-2.61 (0.747)	-2.83 (0.547)	
95% CI [2]	-5.11, -1.02	-6.14, -2.85	-4.09, -1.12	-3.91, -1.74	
Difference (95% CI) in CFB [2]		-1.43 (-3.74, 0.89)		-0.22 (-1.86, 1.42)	
Hedges'G (95% CI) in CFB		-0.24 (-0.70, 0.21)		-0.05 (-0.45, 0.35)	
p-value [3]		0.223		0.792	
					0.414

Skin Domain Score					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	33	58	38	81	
Mean (StdDev)	18.61 (7.438)	15.71 (7.275)	15.96 (7.644)	15.35 (7.055)	
Median	18.29	14.70	17.82	16.17	
Min, Max	1.1, 30.0	2.4, 30.0	0.0, 30.0	0.0, 29.8	

Skin Domain Score					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	33	59	38	78	
Mean (StdDev)	17.07 (7.326)	13.56 (6.547)	14.39 (7.443)	12.45 (6.280)	
Median	16.79	13.00	15.18	12.67	
Min, Max	2.8, 29.8	0.0, 27.4	0.0, 29.8	0.0, 28.5	
C2D1 CFB					
n	33	57	38	78	
LS Mean (StdErr) [2]	-1.74 (0.552)	-2.54 (0.461)	-1.32 (0.711)	-2.73 (0.533)	
95% CI [2]	-2.84, -0.65	-3.46, -1.63	-2.73, 0.09	-3.79, -1.68	
Difference (95% CI) in CFB [2]		-0.80 (-2.05, 0.45)		-1.42 (-2.98, 0.15)	
p-value [3]		0.207		0.076	

Skin Domain Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	33	58	38	77	
Mean (StdDev)	16.80 (7.749)	11.99 (6.534)	13.63 (7.364)	11.06 (6.103)	
Median	16.71	11.33	13.75	10.14	
Min, Max	2.2, 29.4	0.1, 25.4	0.0, 28.9	0.0, 28.1	
C3D1 CFB					
n	33	56	38	77	
LS Mean (StdErr) [2]	-1.66 (0.666)	-3.75 (0.558)	-1.86 (0.907)	-3.96 (0.680)	
95% CI [2]	-2.99, -0.34	-4.85, -2.64	-3.66, -0.06	-5.31, -2.62	
Difference (95% CI) in CFB [2]		-2.08 (-3.60, -0.57)		-2.10 (-4.11, -0.10)	
p-value [3]		0.008		0.040	

Skin Domain Score					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	31	58	37	77	
Mean (StdDev)	16.42 (8.011)	11.35 (6.527)	13.63 (7.379)	10.42 (6.306)	
Median	16.29	11.04	14.21	9.57	
Min, Max	2.8, 29.6	0.0, 24.5	0.0, 29.7	0.0, 28.6	
C4D1 CFB					
n	31	56	37	77	
LS Mean (StdErr) [2]	-2.41 (0.832)	-4.55 (0.674)	-1.53 (0.950)	-4.46 (0.706)	
95% CI [2]	-4.07, -0.76	-5.89, -3.21	-3.41, 0.35	-5.86, -3.06	
Difference (95% CI) in CFB [2]		-2.14 (-3.99, -0.28)		-2.93 (-5.03, -0.84)	
p-value [3]		0.025		0.006	

Skin Domain Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	30	59	37	78	
Mean (StdDev)	16.65 (8.300)	10.52 (6.052)	13.38 (7.231)	10.09 (6.342)	
Median	17.14	9.79	14.50	8.82	
Min, Max	1.4, 30.0	0.1, 25.2	0.0, 29.9	0.1, 28.5	
C5D1 CFB					
n	30	57	37	78	
LS Mean (StdErr) [2]	-2.27 (0.871)	-5.45 (0.680)	-1.84 (1.040)	-4.76 (0.769)	
95% CI [2]	-4.01, -0.54	-6.80, -4.09	-3.90, 0.22	-6.28, -3.24	
Difference (95% CI) in CFB [2]		-3.17 (-5.12, -1.23)		-2.92 (-5.20, -0.63)	
p-value [3]		0.002		0.013	

Skin Domain Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	29	58	37	78	
Mean (StdDev)	16.40 (7.800)	10.27 (5.979)	13.44 (7.584)	9.67 (6.622)	
Median	17.00	9.68	13.00	8.02	
Min, Max	2.0, 30.0	0.1, 24.9	0.0, 29.6	0.0, 30.0	
C6D1 CFB					
n	29	56	37	78	
LS Mean (StdErr) [2]	-2.62 (0.973)	-5.55 (0.757)	-1.68 (1.108)	-5.12 (0.817)	
95% CI [2]	-4.55, -0.68	-7.06, -4.05	-3.88, 0.52	-6.74, -3.50	
Difference (95% CI) in CFB [2]		-2.94 (-5.13, -0.75)		-3.44 (-5.88, -1.00)	
p-value [3]		0.009		0.006	

Skin Domain Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	30	57	36	76	
Mean (StdDev)	16.38 (8.103)	9.53 (6.082)	13.81 (6.702)	9.84 (6.597)	
Median	16.20	8.42	13.36	7.54	
Min, Max	1.2, 30.0	0.1, 24.1	1.4, 30.0	0.0, 30.0	
C7D1 CFB					
n	30	55	36	76	
LS Mean (StdErr) [2]	-2.81 (1.010)	-6.33 (0.811)	-1.43 (1.099)	-4.76 (0.804)	
95% CI [2]	-4.82, -0.80	-7.94, -4.72	-3.61, 0.75	-6.35, -3.17	
Difference (95% CI) in CFB [2]		-3.52 (-5.79, -1.25)		-3.33 (-5.75, -0.91)	
Hedges'G (95% CI) in CFB		-0.60 (-1.07, -0.15)		-0.48 (-0.90, -0.08)	
p-value [3]		0.003		0.007	
					0.898

Neurocognitive Symptom Cluster					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	33	58	38	81	
Mean (StdDev)	13.59 (6.998)	12.86 (5.927)	11.94 (6.945)	13.17 (7.362)	
Median	12.36	13.08	11.04	12.50	
Min, Max	0.4, 29.1	2.2, 26.6	1.6, 24.5	0.0, 29.6	

Neurocognitive Symptom Cluster					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	33	59	38	78	
Mean (StdDev)	11.63 (6.995)	11.49 (5.790)	11.26 (6.582)	11.15 (7.298)	
Median	10.23	11.50	9.68	9.21	
Min, Max	0.2, 27.4	1.1, 26.4	0.4, 24.4	0.0, 30.0	
C2D1 CFB					
n	33	57	38	78	
LS Mean (StdErr) [2]	-2.32 (0.502)	-1.98 (0.420)	-0.25 (0.564)	-1.62 (0.422)	
95% CI [2]	-3.32, -1.33	-2.81, -1.14	-1.37, 0.87	-2.45, -0.78	
Difference (95% CI) in CFB [2]		0.35 (-0.79, 1.49)		-1.37 (-2.61, -0.13)	
p-value [3]		0.547		0.031	

Neurocognitive Symptom Cluster					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	33	58	38	77	
Mean (StdDev)	11.25 (6.649)	10.51 (5.572)	9.82 (6.600)	10.17 (7.338)	
Median	10.29	9.89	8.75	8.57	
Min, Max	0.1, 27.3	1.1, 26.1	0.3, 22.5	0.0, 30.0	
C3D1 CFB					
n	33	56	38	77	
LS Mean (StdErr) [2]	-2.59 (0.666)	-2.84 (0.558)	-1.64 (0.702)	-2.59 (0.526)	
95% CI [2]	-3.91, -1.26	-3.95, -1.73	-3.03, -0.24	-3.63, -1.55	
Difference (95% CI) in CFB [2]		-0.25 (-1.77, 1.26)		-0.95 (-2.50, 0.60)	
p-value [3]		0.740		0.226	

Neurocognitive Symptom Cluster	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	31	58	37	77	
Mean (StdDev)	10.55 (6.518)	9.69 (5.884)	10.40 (6.797)	9.98 (7.328)	
Median	8.50	8.86	9.93	8.45	
Min, Max	0.6, 25.6	0.1, 25.6	0.0, 25.1	0.0, 29.9	
C4D1 CFB					
n	31	56	37	77	
LS Mean (StdErr) [2]	-3.53 (0.844)	-3.93 (0.683)	-1.26 (0.779)	-2.86 (0.579)	
95% CI [2]	-5.21, -1.85	-5.29, -2.57	-2.80, 0.28	-4.01, -1.72	
Difference (95% CI) in CFB [2]		-0.40 (-2.29, 1.48)		-1.60 (-3.32, 0.11)	
p-value [3]		0.671		0.067	

Neurocognitive Symptom Cluster					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	30	59	37	78	
Mean (StdDev)	10.57 (7.238)	9.36 (5.710)	10.00 (6.375)	9.79 (7.318)	
Median	9.43	8.00	9.57	8.00	
Min, Max	0.5, 26.2	1.7, 25.8	0.0, 23.2	0.0, 30.0	
C5D1 CFB					
n	30	57	37	78	
LS Mean (StdErr) [2]	-3.55 (0.846)	-4.09 (0.660)	-1.40 (0.819)	-2.83 (0.606)	
95% CI [2]	-5.23, -1.87	-5.40, -2.77	-3.03, 0.22	-4.03, -1.63	
Difference (95% CI) in CFB [2]		-0.54 (-2.43, 1.35)		-1.43 (-3.23, 0.37)	
p-value [3]		0.573		0.118	

Neurocognitive Symptom Cluster

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	29	58	37	78	
Mean (StdDev)	9.95 (6.678)	8.80 (5.457)	9.69 (6.284)	9.11 (7.500)	
Median	8.55	7.73	8.86	6.76	
Min, Max	0.1, 23.4	0.6, 26.2	0.0, 25.0	0.0, 30.0	
C6D1 CFB					
n	29	56	37	78	
LS Mean (StdErr) [2]	-3.85 (0.893)	-4.53 (0.696)	-1.79 (0.840)	-3.52 (0.619)	
95% CI [2]	-5.62, -2.07	-5.92, -3.15	-3.45, -0.12	-4.75, -2.30	
Difference (95% CI) in CFB [2]		-0.69 (-2.70, 1.32)		-1.73 (-3.58, 0.11)	
p-value [3]		0.497		0.065	

Neurocognitive Symptom Cluster					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	30	57	36	76	
Mean (StdDev)	10.41 (6.991)	8.47 (5.595)	9.54 (6.308)	9.23 (7.436)	
Median	8.37	8.21	8.16	7.48	
Min, Max	0.0, 23.1	0.1, 26.6	0.0, 23.4	0.0, 30.0	
C7D1 CFB					
n	30	55	36	76	
LS Mean (StdErr) [2]	-3.79 (0.941)	-4.84 (0.755)	-1.66 (0.850)	-3.33 (0.622)	
95% CI [2]	-5.66, -1.91	-6.35, -3.34	-3.34, 0.02	-4.56, -2.10	
Difference (95% CI) in CFB [2]		-1.06 (-3.17, 1.05)		-1.67 (-3.54, 0.20)	
Hedges'G (95% CI) in CFB		-0.19 (-0.65, 0.25)		-0.31 (-0.72, 0.08)	
p-value [3]		0.322		0.079	
					0.647

Gastrointestinal Domain Score						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Gastrointestinal Domain Score						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Gastrointestinal Domain Score						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Gastrointestinal Domain Score						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Gastrointestinal Domain Score

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Skin Domain Score						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Skin Domain Score						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Skin Domain Score						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Skin Domain Score						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Skin Domain Score			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Neurocognitive Symptom Cluster						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Neurocognitive Symptom Cluster						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Neurocognitive Symptom Cluster						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Neurocognitive Symptom Cluster						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Neurocognitive Symptom Cluster			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Gastrointestinal Domain Score					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	26	52	45	87	
Mean (StdDev)	5.08 (3.809)	5.70 (3.380)	13.49 (6.314)	12.11 (6.278)	
Median	3.97	5.20	12.14	11.86	
Min, Max	0.0, 13.3	0.0, 14.8	0.1, 28.0	1.0, 26.8	

Gastrointestinal Domain Score					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	26	50	45	85	
Mean (StdDev)	4.33 (3.333)	4.33 (3.163)	10.86 (6.497)	10.07 (6.010)	
Median	3.93	3.85	8.79	8.92	
Min, Max	0.0, 10.4	0.0, 15.1	0.6, 26.4	0.3, 24.0	
C2D1 CFB					
n	26	50	45	85	
LS Mean (StdErr) [2]	-0.49 (0.482)	-0.97 (0.356)	-2.59 (0.497)	-2.09 (0.399)	
95% CI [2]	-1.45, 0.47	-1.68, -0.26	-3.57, -1.61	-2.88, -1.30	
Difference (95% CI) in CFB [2]		-0.48 (-1.54, 0.58)		0.50 (-0.65, 1.64)	
p-value [3]		0.371		0.392	

Gastrointestinal Domain Score					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	26	50	45	83	
Mean (StdDev)	4.07 (3.495)	4.36 (3.668)	9.99 (6.588)	8.72 (5.916)	
Median	3.79	3.07	8.57	8.21	
Min, Max	0.0, 10.2	0.0, 15.4	0.5, 23.9	0.0, 24.0	
C3D1 CFB					
n	26	50	45	83	
LS Mean (StdErr) [2]	-0.93 (0.583)	-1.08 (0.431)	-3.61 (0.656)	-3.59 (0.530)	
95% CI [2]	-2.09, 0.23	-1.94, -0.22	-4.91, -2.31	-4.64, -2.54	
Difference (95% CI) in CFB [2]		-0.14 (-1.42, 1.13)		0.02 (-1.50, 1.53)	
p-value [3]		0.823		0.981	

Gastrointestinal Domain Score					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	24	49	44	84	
Mean (StdDev)	4.20 (3.827)	3.50 (3.016)	10.10 (6.342)	8.22 (6.110)	
Median	3.11	3.31	9.54	6.59	
Min, Max	0.0, 12.4	0.0, 9.4	0.5, 23.5	0.0, 24.8	
C4D1 CFB					
n	24	49	44	84	
LS Mean (StdErr) [2]	-0.77 (0.631)	-1.75 (0.457)	-3.75 (0.764)	-4.27 (0.605)	
95% CI [2]	-2.03, 0.49	-2.66, -0.84	-5.26, -2.24	-5.47, -3.07	
Difference (95% CI) in CFB [2]		-0.98 (-2.37, 0.41)		-0.52 (-2.26, 1.21)	
p-value [3]		0.165		0.554	

Gastrointestinal Domain Score					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	51	44	84	
Mean (StdDev)	4.47 (3.610)	3.73 (3.473)	10.05 (6.101)	7.83 (6.356)	
Median	5.27	2.85	8.70	6.77	
Min, Max	0.0, 10.4	0.0, 14.1	0.8, 23.3	0.0, 25.0	
C5D1 CFB					
n	23	51	44	84	
LS Mean (StdErr) [2]	-0.33 (0.683)	-1.49 (0.476)	-3.93 (0.826)	-4.81 (0.655)	
95% CI [2]	-1.69, 1.03	-2.43, -0.54	-5.57, -2.30	-6.11, -3.52	
Difference (95% CI) in CFB [2]		-1.16 (-2.66, 0.34)		-0.88 (-2.76, 1.00)	
p-value [3]		0.129		0.355	

Gastrointestinal Domain Score					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	24	52	42	82	
Mean (StdDev)	4.11 (3.785)	3.57 (3.459)	8.80 (6.255)	7.32 (6.214)	
Median	2.86	3.35	7.18	6.25	
Min, Max	0.0, 12.1	0.0, 16.2	0.2, 20.8	0.0, 25.5	
C6D1 CFB					
n	24	52	42	82	
LS Mean (StdErr) [2]	-0.50 (0.614)	-1.98 (0.432)	-4.96 (0.844)	-5.11 (0.662)	
95% CI [2]	-1.73, 0.72	-2.84, -1.12	-6.63, -3.29	-6.42, -3.79	
Difference (95% CI) in CFB [2]		-1.48 (-2.83, -0.13)		-0.14 (-2.07, 1.78)	
p-value [3]		0.032		0.884	

Gastrointestinal Domain Score					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	23	51	43	80	
Mean (StdDev)	3.59 (3.429)	3.62 (3.210)	9.39 (6.481)	7.32 (6.257)	
Median	2.43	3.21	8.14	5.72	
Min, Max	0.0, 11.1	0.0, 12.0	0.1, 22.9	0.0, 26.4	
C7D1 CFB					
n	23	51	43	80	
LS Mean (StdErr) [2]	-0.68 (0.576)	-1.70 (0.401)	-4.55 (0.894)	-5.17 (0.720)	
95% CI [2]	-1.83, 0.47	-2.50, -0.90	-6.32, -2.77	-6.59, -3.74	
Difference (95% CI) in CFB [2]		-1.02 (-2.29, 0.25)		-0.62 (-2.67, 1.42)	
Hedges'G (95% CI) in CFB		-0.36 (-0.87, 0.14)		-0.10 (-0.48, 0.27)	
p-value [3]		0.112		0.548	
					0.801

Skin Domain Score					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	26	52	45	87	
Mean (StdDev)	12.02 (7.450)	10.21 (5.728)	20.18 (5.974)	18.66 (5.909)	
Median	11.79	9.67	20.71	18.43	
Min, Max	0.0, 27.0	0.0, 22.8	2.2, 30.0	3.9, 30.0	

Skin Domain Score					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	26	50	45	85	
Mean (StdDev)	10.78 (6.974)	8.28 (5.322)	18.44 (6.236)	15.55 (5.307)	
Median	9.53	7.78	17.14	15.46	
Min, Max	0.0, 26.5	0.0, 21.8	2.3, 29.8	2.2, 28.5	
C2D1 CFB					
n	26	50	45	85	
LS Mean (StdErr) [2]	-1.43 (0.659)	-2.01 (0.488)	-1.81 (0.611)	-3.27 (0.491)	
95% CI [2]	-2.75, -0.12	-2.98, -1.04	-3.02, -0.61	-4.24, -2.30	
Difference (95% CI) in CFB [2]		-0.58 (-2.02, 0.87)		-1.46 (-2.86, -0.05)	
p-value [3]		0.430		0.042	

Skin Domain Score					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	26	50	45	83	
Mean (StdDev)	10.48 (7.172)	7.77 (5.036)	17.77 (6.646)	13.59 (5.924)	
Median	8.21	7.00	16.79	12.79	
Min, Max	0.0, 27.5	0.0, 20.7	2.0, 29.4	1.5, 28.1	
C3D1 CFB					
n	26	50	45	83	
LS Mean (StdErr) [2]	-1.82 (0.883)	-2.60 (0.654)	-2.28 (0.739)	-5.11 (0.597)	
95% CI [2]	-3.59, -0.06	-3.90, -1.30	-3.74, -0.82	-6.29, -3.92	
Difference (95% CI) in CFB [2]		-0.77 (-2.71, 1.17)		-2.83 (-4.53, -1.12)	
p-value [3]		0.429		0.001	

Skin Domain Score					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	24	49	44	84	
Mean (StdDev)	9.74 (7.022)	7.09 (4.696)	17.71 (6.639)	12.86 (6.277)	
Median	7.29	6.25	18.03	12.66	
Min, Max	0.0, 25.5	0.0, 20.3	2.8, 29.7	1.7, 28.6	
C4D1 CFB					
n	24	49	44	84	
LS Mean (StdErr) [2]	-1.93 (0.851)	-3.11 (0.617)	-2.39 (0.860)	-5.74 (0.682)	
95% CI [2]	-3.62, -0.23	-4.34, -1.88	-4.10, -0.69	-7.09, -4.39	
Difference (95% CI) in CFB [2]		-1.18 (-3.06, 0.69)		-3.34 (-5.30, -1.39)	
p-value [3]		0.213		<0.001	

Skin Domain Score					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	51	44	84	
Mean (StdDev)	10.04 (7.478)	6.96 (4.285)	17.36 (6.849)	12.16 (6.324)	
Median	7.36	6.14	17.14	11.37	
Min, Max	0.0, 23.6	0.1, 19.0	2.5, 30.0	0.3, 28.5	
C5D1 CFB					
n	23	51	44	84	
LS Mean (StdErr) [2]	-1.74 (0.920)	-3.45 (0.640)	-2.85 (0.929)	-6.56 (0.737)	
95% CI [2]	-3.57, 0.09	-4.73, -2.17	-4.69, -1.01	-8.01, -5.10	
Difference (95% CI) in CFB [2]		-1.71 (-3.73, 0.31)		-3.71 (-5.82, -1.59)	
p-value [3]		0.097		<0.001	

Skin Domain Score					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	24	52	42	82	
Mean (StdDev)	10.38 (6.888)	6.65 (3.991)	17.24 (7.170)	11.90 (6.684)	
Median	9.36	6.04	17.41	11.00	
Min, Max	0.0, 22.9	0.0, 17.9	2.0, 30.0	0.7, 30.0	
C6D1 CFB					
n	24	52	42	82	
LS Mean (StdErr) [2]	-1.83 (0.964)	-3.58 (0.678)	-2.83 (1.030)	-6.91 (0.809)	
95% CI [2]	-3.76, 0.09	-4.93, -2.22	-4.87, -0.79	-8.51, -5.30	
Difference (95% CI) in CFB [2]		-1.74 (-3.86, 0.37)		-4.08 (-6.43, -1.73)	
p-value [3]		0.105		<0.001	

Skin Domain Score					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	23	51	43	80	
Mean (StdDev)	10.93 (6.185)	6.94 (4.351)	17.15 (7.177)	11.39 (6.776)	
Median	10.43	6.43	17.00	10.92	
Min, Max	1.4, 23.0	0.0, 19.1	1.2, 30.0	0.0, 30.0	
C7D1 CFB					
n	23	51	43	80	
LS Mean (StdErr) [2]	-1.86 (0.921)	-3.33 (0.641)	-2.97 (1.038)	-7.38 (0.836)	
95% CI [2]	-3.70, -0.03	-4.60, -2.05	-5.03, -0.92	-9.04, -5.73	
Difference (95% CI) in CFB [2]		-1.46 (-3.49, 0.56)		-4.41 (-6.79, -2.04)	
Hedges'G (95% CI) in CFB		-0.32 (-0.83, 0.17)		-0.60 (-1.00, -0.23)	
p-value [3]		0.154		<0.001	
					0.096

Neurocognitive Symptom Cluster					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	26	52	45	87	
Mean (StdDev)	7.57 (4.144)	7.47 (3.597)	15.67 (6.552)	16.36 (6.013)	
Median	7.88	7.50	13.85	15.31	
Min, Max	0.4, 20.0	0.0, 15.4	5.2, 29.1	1.9, 29.6	

Neurocognitive Symptom Cluster					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	26	50	45	85	
Mean (StdDev)	6.75 (4.222)	6.46 (3.592)	14.13 (6.444)	14.07 (6.523)	
Median	6.64	5.54	12.29	12.86	
Min, Max	0.2, 19.8	0.0, 16.8	3.4, 27.4	0.0, 30.0	
C2D1 CFB					
n	26	50	45	85	
LS Mean (StdErr) [2]	-0.77 (0.494)	-0.97 (0.366)	-1.67 (0.535)	-2.47 (0.430)	
95% CI [2]	-1.76, 0.21	-1.70, -0.24	-2.73, -0.61	-3.32, -1.62	
Difference (95% CI) in CFB [2]		-0.19 (-1.28, 0.89)		-0.80 (-2.03, 0.43)	
p-value [3]		0.722		0.199	

Neurocognitive Symptom Cluster					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	26	50	45	83	
Mean (StdDev)	6.17 (4.497)	5.89 (3.368)	12.97 (6.388)	12.88 (6.762)	
Median	5.37	5.18	11.64	12.11	
Min, Max	0.1, 19.8	0.0, 16.1	1.4, 27.3	0.0, 30.0	
C3D1 CFB					
n	26	50	45	83	
LS Mean (StdErr) [2]	-1.66 (0.638)	-1.79 (0.472)	-2.71 (0.665)	-3.59 (0.537)	
95% CI [2]	-2.93, -0.39	-2.73, -0.85	-4.03, -1.39	-4.65, -2.52	
Difference (95% CI) in CFB [2]		-0.13 (-1.53, 1.27)		-0.88 (-2.41, 0.66)	
p-value [3]		0.853		0.261	

Neurocognitive Symptom Cluster					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	24	49	44	84	
Mean (StdDev)	6.54 (4.814)	5.44 (3.628)	12.61 (6.530)	12.32 (6.870)	
Median	5.87	4.71	10.82	11.36	
Min, Max	0.0, 19.2	0.1, 17.7	1.3, 25.6	0.0, 29.9	
C4D1 CFB					
n	24	49	44	84	
LS Mean (StdErr) [2]	-0.95 (0.681)	-1.97 (0.494)	-3.38 (0.801)	-4.46 (0.635)	
95% CI [2]	-2.31, 0.41	-2.95, -0.98	-4.96, -1.79	-5.71, -3.20	
Difference (95% CI) in CFB [2]		-1.02 (-2.52, 0.48)		-1.08 (-2.90, 0.74)	
p-value [3]		0.180		0.243	

Neurocognitive Symptom Cluster					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	51	44	84	
Mean (StdDev)	5.68 (4.465)	5.70 (3.942)	12.65 (6.498)	11.86 (6.936)	
Median	5.36	4.73	11.10	10.85	
Min, Max	0.0, 17.4	0.0, 16.3	1.5, 26.2	0.0, 30.0	
C5D1 CFB					
n	23	51	44	84	
LS Mean (StdErr) [2]	-1.63 (0.749)	-1.69 (0.522)	-3.25 (0.808)	-4.82 (0.641)	
95% CI [2]	-3.12, -0.13	-2.73, -0.65	-4.85, -1.65	-6.09, -3.56	
Difference (95% CI) in CFB [2]		-0.06 (-1.71, 1.59)		-1.57 (-3.41, 0.27)	
p-value [3]		0.940		0.093	

Neurocognitive Symptom Cluster					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	24	52	42	82	
Mean (StdDev)	6.22 (4.613)	5.40 (3.741)	11.85 (6.435)	11.18 (7.228)	
Median	6.01	4.73	10.39	10.89	
Min, Max	0.0, 17.0	0.0, 15.7	1.3, 25.0	0.0, 30.0	
C6D1 CFB					
n	24	52	42	82	
LS Mean (StdErr) [2]	-1.31 (0.713)	-2.17 (0.502)	-4.02 (0.876)	-5.57 (0.687)	
95% CI [2]	-2.73, 0.11	-3.17, -1.17	-5.75, -2.29	-6.93, -4.21	
Difference (95% CI) in CFB [2]		-0.86 (-2.43, 0.70)		-1.55 (-3.55, 0.45)	
p-value [3]		0.276		0.127	

Neurocognitive Symptom Cluster					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	23	51	43	80	
Mean (StdDev)	6.10 (4.320)	5.46 (3.955)	11.99 (6.712)	11.05 (7.234)	
Median	6.08	4.25	11.33	10.35	
Min, Max	0.0, 16.6	0.0, 14.0	1.2, 23.4	0.0, 30.0	
C7D1 CFB					
n	23	51	43	80	
LS Mean (StdErr) [2]	-1.27 (0.789)	-2.17 (0.550)	-3.98 (0.875)	-5.60 (0.705)	
95% CI [2]	-2.84, 0.31	-3.27, -1.08	-5.71, -2.25	-6.99, -4.20	
Difference (95% CI) in CFB [2]		-0.91 (-2.64, 0.83)		-1.62 (-3.62, 0.38)	
Hedges'G (95% CI) in CFB		-0.23 (-0.74, 0.26)		-0.26 (-0.64, 0.11)	
p-value [3]		0.301		0.112	
					0.630

Gastrointestinal Domain Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	15	28	56	111	
Mean (StdDev)	12.21 (7.079)	9.79 (7.196)	9.93 (6.767)	9.69 (5.961)	
Median	10.14	8.31	9.75	9.07	
Min, Max	2.9, 24.9	0.9, 26.3	0.0, 28.0	0.0, 26.8	

Gastrointestinal Domain Score					
	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	56	110	
Mean (StdDev)	8.46 (6.359)	9.49 (6.983)	8.47 (6.426)	7.65 (5.487)	
Median	6.75	6.57	7.79	6.92	
Min, Max	1.2, 22.1	1.1, 21.4	0.0, 26.4	0.0, 24.0	
C2D1 CFB					
n	15	27	56	108	
LS Mean (StdErr) [2]	-3.44 (0.851)	-0.27 (0.616)	-1.34 (0.352)	-1.98 (0.258)	
95% CI [2]	-5.16, -1.72	-1.52, 0.98	-2.03, -0.64	-2.49, -1.47	
Difference (95% CI) in CFB [2]		3.17 (1.09, 5.25)		-0.64 (-1.49, 0.21)	
p-value [3]		0.004		0.140	

Gastrointestinal Domain Score					
	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	27	56	108	
Mean (StdDev)	7.24 (6.045)	8.33 (6.369)	7.98 (6.430)	6.87 (5.369)	
Median	5.77	7.38	7.24	6.19	
Min, Max	1.7, 21.6	0.1, 22.2	0.0, 23.9	0.0, 24.0	
C3D1 CFB					
n	15	27	56	106	
LS Mean (StdErr) [2]	-4.39 (0.858)	-1.33 (0.621)	-1.72 (0.493)	-2.56 (0.364)	
95% CI [2]	-6.13, -2.66	-2.59, -0.07	-2.69, -0.74	-3.28, -1.84	
Difference (95% CI) in CFB [2]		3.06 (0.96, 5.16)		-0.84 (-2.04, 0.35)	
p-value [3]		0.005		0.165	

Gastrointestinal Domain Score					
	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	14	27	54	108	
Mean (StdDev)	7.26 (5.848)	7.67 (6.243)	8.21 (6.373)	6.27 (5.493)	
Median	5.86	6.45	7.31	5.00	
Min, Max	1.2, 19.3	0.0, 24.1	0.0, 23.5	0.0, 24.8	
C4D1 CFB					
n	14	27	54	106	
LS Mean (StdErr) [2]	-4.69 (1.031)	-1.95 (0.727)	-1.67 (0.567)	-3.22 (0.411)	
95% CI [2]	-6.77, -2.60	-3.42, -0.48	-2.79, -0.55	-4.03, -2.41	
Difference (95% CI) in CFB [2]		2.74 (0.23, 5.24)		-1.55 (-2.91, -0.20)	
p-value [3]		0.033		0.025	

Gastrointestinal Domain Score					
	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	28	53	109	
Mean (StdDev)	7.06 (5.015)	7.45 (5.542)	8.42 (6.218)	6.09 (5.846)	
Median	5.86	6.59	7.50	4.64	
Min, Max	1.7, 17.3	0.0, 21.1	0.0, 23.3	0.0, 25.0	
C5D1 CFB					
n	14	28	53	107	
LS Mean (StdErr) [2]	-4.61 (1.197)	-2.03 (0.826)	-1.52 (0.609)	-3.42 (0.433)	
95% CI [2]	-7.04, -2.19	-3.70, -0.36	-2.73, -0.32	-4.28, -2.56	
Difference (95% CI) in CFB [2]		2.58 (-0.32, 5.48)		-1.90 (-3.35, -0.45)	
p-value [3]		0.080		0.011	

Gastrointestinal Domain Score					
	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	28	52	108	
Mean (StdDev)	6.55 (5.478)	6.92 (5.916)	7.24 (6.063)	5.60 (5.471)	
Median	4.22	5.68	5.43	4.31	
Min, Max	0.5, 16.4	0.0, 22.7	0.0, 20.8	0.0, 25.5	
C6D1 CFB					
n	14	28	52	106	
LS Mean (StdErr) [2]	-5.20 (1.247)	-2.59 (0.860)	-2.19 (0.597)	-3.68 (0.423)	
95% CI [2]	-7.72, -2.68	-4.33, -0.85	-3.37, -1.01	-4.51, -2.84	
Difference (95% CI) in CFB [2]		2.61 (-0.41, 5.63)		-1.49 (-2.92, -0.06)	
p-value [3]		0.089		0.041	

Gastrointestinal Domain Score					
	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	14	27	52	106	
Mean (StdDev)	6.93 (5.185)	6.80 (5.913)	7.49 (6.529)	5.69 (5.443)	
Median	5.61	5.43	6.13	4.33	
Min, Max	0.5, 16.1	0.0, 26.4	0.0, 22.9	0.0, 24.9	
C7D1 CFB					
n	14	27	52	104	
LS Mean (StdErr) [2]	-4.79 (1.332)	-2.43 (0.932)	-2.10 (0.625)	-3.67 (0.446)	
95% CI [2]	-7.48, -2.09	-4.32, -0.54	-3.33, -0.86	-4.56, -2.79	
Difference (95% CI) in CFB [2]		2.36 (-0.90, 5.61)		-1.58 (-3.07, -0.08)	
Hedges'G (95% CI) in CFB		0.47 (-0.18, 1.17)		-0.35 (-0.69, -0.01)	
p-value [3]		0.151		0.038	
					0.016

Skin Domain Score					
	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	15	28	56	111	
Mean (StdDev)	15.98 (6.914)	15.84 (7.165)	17.52 (7.815)	15.41 (7.143)	
Median	16.43	15.51	18.32	15.15	
Min, Max	1.9, 24.4	1.9, 29.8	0.0, 30.0	0.0, 30.0	

Skin Domain Score					
	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	56	110	
Mean (StdDev)	13.52 (6.671)	13.28 (6.288)	16.20 (7.611)	12.84 (6.448)	
Median	13.71	12.50	16.46	12.78	
Min, Max	2.8, 23.0	1.0, 23.4	0.0, 29.8	0.0, 28.5	
C2D1 CFB					
n	15	27	56	108	
LS Mean (StdErr) [2]	-2.29 (1.069)	-2.56 (0.774)	-1.20 (0.464)	-2.56 (0.341)	
95% CI [2]	-4.45, -0.13	-4.13, -1.00	-2.12, -0.28	-3.23, -1.88	
Difference (95% CI) in CFB [2]		-0.27 (-2.88, 2.34)		-1.35 (-2.48, -0.23)	
p-value [3]		0.834		0.018	

Skin Domain Score					
	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	27	56	108	
Mean (StdDev)	12.98 (6.566)	12.32 (6.223)	15.67 (7.880)	11.24 (6.310)	
Median	13.92	12.93	16.21	10.04	
Min, Max	3.8, 23.2	2.3, 23.3	0.0, 29.4	0.0, 28.1	
C3D1 CFB					
n	15	27	56	106	
LS Mean (StdErr) [2]	-2.77 (1.210)	-3.49 (0.876)	-1.58 (0.596)	-4.00 (0.440)	
95% CI [2]	-5.22, -0.32	-5.27, -1.72	-2.76, -0.41	-4.87, -3.13	
Difference (95% CI) in CFB [2]		-0.72 (-3.68, 2.24)		-2.42 (-3.86, -0.97)	
p-value [3]		0.624		0.001	

Skin Domain Score					
	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	14	27	54	108	
Mean (StdDev)	12.88 (6.253)	11.99 (6.130)	15.42 (8.052)	10.53 (6.453)	
Median	13.50	13.21	15.96	9.52	
Min, Max	2.8, 22.1	2.5, 22.9	0.0, 29.7	0.0, 28.6	
C4D1 CFB					
n	14	27	54	106	
LS Mean (StdErr) [2]	-2.73 (1.324)	-3.77 (0.934)	-1.89 (0.665)	-4.85 (0.482)	
95% CI [2]	-5.41, -0.05	-5.66, -1.88	-3.21, -0.58	-5.80, -3.90	
Difference (95% CI) in CFB [2]		-1.04 (-4.26, 2.18)		-2.96 (-4.55, -1.37)	
p-value [3]		0.517		<0.001	

Skin Domain Score					
	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	28	53	109	
Mean (StdDev)	11.88 (6.233)	11.28 (5.918)	15.63 (8.081)	10.02 (6.271)	
Median	12.79	11.78	15.92	9.15	
Min, Max	2.5, 18.6	1.9, 23.4	0.0, 30.0	0.1, 28.5	
C5D1 CFB					
n	14	28	53	107	
LS Mean (StdErr) [2]	-3.70 (1.449)	-4.44 (1.000)	-1.58 (0.717)	-5.16 (0.511)	
95% CI [2]	-6.63, -0.77	-6.47, -2.42	-2.99, -0.16	-6.17, -4.15	
Difference (95% CI) in CFB [2]		-0.75 (-4.26, 2.77)		-3.58 (-5.29, -1.87)	
p-value [3]		0.670		<0.0001	

Skin Domain Score					
	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	28	52	108	
Mean (StdDev)	12.13 (5.730)	11.13 (6.370)	15.45 (8.127)	9.61 (6.324)	
Median	12.36	10.74	15.55	8.29	
Min, Max	2.0, 18.2	1.1, 29.4	0.0, 30.0	0.0, 30.0	
C6D1 CFB					
n	14	28	52	106	
LS Mean (StdErr) [2]	-3.35 (1.619)	-4.56 (1.117)	-1.84 (0.774)	-5.58 (0.549)	
95% CI [2]	-6.62, -0.07	-6.82, -2.30	-3.37, -0.31	-6.66, -4.49	
Difference (95% CI) in CFB [2]		-1.21 (-5.14, 2.71)		-3.74 (-5.59, -1.89)	
p-value [3]		0.535		<0.001	

Skin Domain Score					
	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	14	27	52	106	
Mean (StdDev)	12.38 (5.659)	10.88 (6.514)	15.68 (7.731)	9.41 (6.316)	
Median	13.46	10.58	15.23	7.93	
Min, Max	1.2, 20.8	2.3, 28.9	1.4, 30.0	0.0, 30.0	
C7D1 CFB					
n	14	27	52	104	
LS Mean (StdErr) [2]	-3.01 (1.632)	-4.80 (1.143)	-1.93 (0.778)	-5.68 (0.555)	
95% CI [2]	-6.32, 0.29	-7.12, -2.49	-3.47, -0.40	-6.78, -4.59	
Difference (95% CI) in CFB [2]		-1.79 (-5.78, 2.20)		-3.75 (-5.61, -1.89)	
Hedges'G (95% CI) in CFB		-0.29 (-0.98, 0.36)		-0.66 (-1.01, -0.33)	
p-value [3]		0.368		<0.001	
					0.375

Neurocognitive Symptom Cluster					
	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	15	28	56	111	
Mean (StdDev)	14.42 (7.411)	13.79 (7.605)	12.25 (6.842)	12.85 (6.578)	
Median	13.57	12.20	10.89	13.00	
Min, Max	3.5, 26.7	0.5, 28.6	0.4, 29.1	0.0, 29.6	

Neurocognitive Symptom Cluster					
	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	56	110	
Mean (StdDev)	12.24 (6.382)	12.36 (7.422)	11.21 (6.860)	11.04 (6.482)	
Median	10.57	11.93	9.68	10.25	
Min, Max	6.2, 24.9	1.2, 28.1	0.2, 27.4	0.0, 30.0	
C2D1 CFB					
n	15	27	56	108	
LS Mean (StdErr) [2]	-1.83 (0.994)	-1.52 (0.719)	-0.93 (0.378)	-1.74 (0.277)	
95% CI [2]	-3.84, 0.18	-2.97, -0.06	-1.68, -0.19	-2.29, -1.19	
Difference (95% CI) in CFB [2]		0.31 (-2.12, 2.74)		-0.81 (-1.72, 0.10)	
p-value [3]		0.795		0.082	

Neurocognitive Symptom Cluster					
	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	27	56	108	
Mean (StdDev)	10.84 (7.028)	11.58 (7.649)	10.38 (6.562)	10.00 (6.332)	
Median	7.57	9.08	9.11	9.11	
Min, Max	4.5, 23.6	0.3, 27.1	0.1, 27.3	0.0, 30.0	
C3D1 CFB					
n	15	27	56	106	
LS Mean (StdErr) [2]	-3.35 (1.180)	-2.35 (0.854)	-1.66 (0.481)	-2.68 (0.355)	
95% CI [2]	-5.74, -0.97	-4.08, -0.62	-2.61, -0.71	-3.38, -1.98	
Difference (95% CI) in CFB [2]		1.00 (-1.88, 3.89)		-1.01 (-2.18, 0.15)	
p-value [3]		0.487		0.087	

Neurocognitive Symptom Cluster					
	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	14	27	54	108	
Mean (StdDev)	10.07 (6.626)	10.73 (7.184)	10.57 (6.679)	9.64 (6.620)	
Median	7.79	9.69	9.89	8.00	
Min, Max	3.2, 23.0	0.0, 26.6	0.0, 25.6	0.1, 29.9	
C4D1 CFB					
n	14	27	54	106	
LS Mean (StdErr) [2]	-3.61 (1.409)	-3.04 (0.993)	-1.53 (0.567)	-3.00 (0.411)	
95% CI [2]	-6.46, -0.75	-5.05, -1.03	-2.65, -0.41	-3.81, -2.19	
Difference (95% CI) in CFB [2]		0.57 (-2.86, 3.99)		-1.47 (-2.83, -0.11)	
p-value [3]		0.738		0.034	

Neurocognitive Symptom Cluster					
	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	28	53	109	
Mean (StdDev)	9.87 (5.910)	10.79 (6.865)	10.36 (6.977)	9.30 (6.596)	
Median	8.57	9.15	9.64	7.86	
Min, Max	3.1, 22.4	0.0, 23.6	0.0, 26.2	0.0, 30.0	
C5D1 CFB					
n	14	28	53	107	
LS Mean (StdErr) [2]	-3.75 (1.473)	-2.79 (1.016)	-1.80 (0.582)	-3.35 (0.414)	
95% CI [2]	-6.73, -0.77	-4.84, -0.74	-2.95, -0.65	-4.17, -2.53	
Difference (95% CI) in CFB [2]		0.96 (-2.61, 4.53)		-1.55 (-2.94, -0.17)	
p-value [3]		0.590		0.028	

Neurocognitive Symptom Cluster					
	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	28	52	108	
Mean (StdDev)	8.57 (6.181)	10.22 (7.361)	10.14 (6.490)	8.66 (6.495)	
Median	6.64	9.02	8.93	7.41	
Min, Max	1.1, 22.5	0.1, 29.6	0.0, 25.0	0.0, 30.0	
C6D1 CFB					
n	14	28	52	106	
LS Mean (StdErr) [2]	-5.01 (1.579)	-3.34 (1.089)	-1.68 (0.592)	-3.75 (0.420)	
95% CI [2]	-8.20, -1.81	-5.54, -1.14	-2.85, -0.51	-4.58, -2.93	
Difference (95% CI) in CFB [2]		1.67 (-2.16, 5.49)		-2.07 (-3.49, -0.66)	
p-value [3]		0.383		0.004	

Neurocognitive Symptom Cluster					
	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	14	27	52	106	
Mean (StdDev)	9.18 (6.317)	9.77 (7.315)	10.14 (6.706)	8.68 (6.548)	
Median	7.29	8.31	8.90	7.91	
Min, Max	1.2, 22.6	0.0, 29.0	0.0, 23.4	0.0, 30.0	
C7D1 CFB					
n	14	27	52	104	
LS Mean (StdErr) [2]	-4.44 (1.622)	-3.53 (1.135)	-1.78 (0.612)	-3.73 (0.437)	
95% CI [2]	-7.73, -1.16	-5.83, -1.23	-2.99, -0.57	-4.60, -2.87	
Difference (95% CI) in CFB [2]		0.91 (-3.05, 4.87)		-1.95 (-3.41, -0.49)	
Hedges'G (95% CI) in CFB		0.15 (-0.51, 0.83)		-0.44 (-0.78, -0.10)	
p-value [3]		0.644		0.009	
					0.102

Gastrointestinal Domain Score					
	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	67	129	4	10	
Mean (StdDev)	10.35 (6.804)	9.62 (6.158)	11.46 (8.581)	10.89 (6.981)	
Median	9.79	8.38	8.36	11.25	
Min, Max	0.0, 28.0	0.0, 26.8	5.4, 23.8	1.0, 26.3	

Gastrointestinal Domain Score					
	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	67	127	4	10	
Mean (StdDev)	8.40 (6.502)	7.91 (5.778)	9.70 (3.653)	9.32 (6.657)	
Median	7.21	6.79	9.29	9.11	
Min, Max	0.0, 26.4	0.0, 24.0	5.8, 14.4	1.6, 23.0	
C2D1 CFB					
n	67	125	4	10	
LS Mean (StdErr) [2]	-1.69 (0.374)	-1.56 (0.294)	-0.41 (2.491)	-0.18 (1.907)	
95% CI [2]	-2.43, -0.95	-2.14, -0.98	-5.97, 5.14	-4.43, 4.07	
Difference (95% CI) in CFB [2]		0.13 (-0.71, 0.97)		0.23 (-4.37, 4.84)	
p-value [3]		0.758		0.912	

Gastrointestinal Domain Score					
	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	67	125	4	10	
Mean (StdDev)	7.66 (6.432)	7.06 (5.466)	10.52 (3.231)	8.40 (7.174)	
Median	6.31	6.17	9.29	8.02	
Min, Max	0.0, 23.9	0.0, 24.0	8.3, 15.2	0.1, 22.8	
C3D1 CFB					
n	67	123	4	10	
LS Mean (StdErr) [2]	-2.40 (0.482)	-2.37 (0.380)	0.52 (3.023)	-1.26 (2.315)	
95% CI [2]	-3.35, -1.45	-3.12, -1.62	-6.21, 7.26	-6.42, 3.89	
Difference (95% CI) in CFB [2]		0.03 (-1.06, 1.11)		-1.79 (-7.38, 3.81)	
p-value [3]		0.961		0.493	

Gastrointestinal Domain Score					
	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	64	125	4	10	
Mean (StdDev)	7.91 (6.385)	6.52 (5.579)	9.73 (2.956)	7.00 (6.849)	
Median	6.82	5.36	10.54	6.57	
Min, Max	0.0, 23.5	0.0, 24.8	5.5, 12.4	0.0, 23.3	
C4D1 CFB					
n	64	123	4	10	
LS Mean (StdErr) [2]	-2.45 (0.559)	-3.03 (0.431)	0.37 (3.646)	-1.70 (2.791)	
95% CI [2]	-3.55, -1.34	-3.88, -2.18	-7.76, 8.49	-7.92, 4.52	
Difference (95% CI) in CFB [2]		-0.58 (-1.83, 0.66)		-2.07 (-8.81, 4.68)	
p-value [3]		0.356		0.511	

Gastrointestinal Domain Score					
	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	63	127	4	10	
Mean (StdDev)	8.12 (6.156)	6.12 (5.361)	8.46 (1.654)	9.56 (9.604)	
Median	7.14	5.29	7.88	6.11	
Min, Max	0.0, 23.3	0.0, 23.8	7.2, 10.9	0.0, 25.0	
C5D1 CFB					
n	63	125	4	10	
LS Mean (StdErr) [2]	-2.24 (0.578)	-3.42 (0.437)	1.53 (5.178)	2.41 (3.964)	
95% CI [2]	-3.38, -1.10	-4.28, -2.56	-10.00, 13.07	-6.43, 11.24	
Difference (95% CI) in CFB [2]		-1.18 (-2.46, 0.11)		0.87 (-8.71, 10.46)	
p-value [3]		0.072		0.843	

Gastrointestinal Domain Score					
	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	62	126	4	10	
Mean (StdDev)	6.95 (6.044)	5.74 (5.381)	9.29 (2.700)	7.61 (7.705)	
Median	4.78	4.35	9.61	6.82	
Min, Max	0.0, 20.8	0.0, 25.5	5.9, 12.1	0.0, 25.4	
C6D1 CFB					
n	62	124	4	10	
LS Mean (StdErr) [2]	-3.03 (0.595)	-3.66 (0.449)	2.25 (3.761)	0.92 (2.880)	
95% CI [2]	-4.21, -1.86	-4.55, -2.77	-6.13, 10.63	-5.49, 7.34	
Difference (95% CI) in CFB [2]		-0.63 (-1.96, 0.70)		-1.33 (-8.29, 5.63)	
p-value [3]		0.352		0.680	

Gastrointestinal Domain Score					
	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	63	123	3	10	
Mean (StdDev)	7.32 (6.363)	5.85 (5.417)	8.43 (2.536)	6.77 (7.139)	
Median	5.91	4.64	9.86	4.14	
Min, Max	0.0, 22.9	0.0, 26.4	5.5, 9.9	0.4, 23.9	
C7D1 CFB					
n	63	121	3	10	
LS Mean (StdErr) [2]	-2.79 (0.627)	-3.52 (0.481)	1.48 (4.026)	-0.11 (2.816)	
95% CI [2]	-4.03, -1.56	-4.47, -2.57	-7.63, 10.58	-6.48, 6.27	
Difference (95% CI) in CFB [2]		-0.72 (-2.13, 0.68)		-1.58 (-9.10, 5.93)	
Hedges'G (95% CI) in CFB		-0.14 (-0.45, 0.17)		-0.17 (-1.66, 1.24)	
p-value [3]		0.310		0.645	
					0.990

Skin Domain Score					
	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	67	129	4	10	
Mean (StdDev)	17.49 (7.381)	15.37 (7.049)	12.27 (10.922)	17.21 (8.243)	
Median	18.29	14.85	11.82	18.50	
Min, Max	1.1, 30.0	0.0, 30.0	0.0, 25.4	2.7, 28.9	

Skin Domain Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	67	127	4	10	
Mean (StdDev)	15.89 (7.357)	12.83 (6.280)	11.39 (9.060)	14.11 (8.027)	
Median	16.38	12.57	12.50	14.29	
Min, Max	2.1, 29.8	0.0, 27.4	0.0, 20.6	2.1, 28.5	
C2D1 CFB					
n	67	125	4	10	
LS Mean (StdErr) [2]	-1.58 (0.470)	-2.66 (0.370)	0.81 (3.124)	-1.33 (2.392)	
95% CI [2]	-2.51, -0.66	-3.39, -1.93	-6.15, 7.77	-6.66, 4.00	
Difference (95% CI) in CFB [2]		-1.08 (-2.14, -0.03)		-2.14 (-7.92, 3.64)	
p-value [3]		0.044		0.429	

Skin Domain Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	67	125	4	10	
Mean (StdDev)	15.40 (7.603)	11.28 (6.112)	10.23 (7.930)	13.72 (8.197)	
Median	15.15	10.46	12.11	13.31	
Min, Max	1.8, 29.4	0.0, 25.4	0.0, 16.7	3.1, 28.1	
C3D1 CFB					
n	67	123	4	10	
LS Mean (StdErr) [2]	-1.79 (0.590)	-3.98 (0.465)	0.73 (3.705)	-0.60 (2.837)	
95% CI [2]	-2.95, -0.62	-4.89, -3.06	-7.53, 8.99	-6.92, 5.73	
Difference (95% CI) in CFB [2]		-2.19 (-3.51, -0.86)		-1.32 (-8.18, 5.53)	
p-value [3]		0.001		0.676	

Skin Domain Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	64	125	4	10	
Mean (StdDev)	15.22 (7.680)	10.64 (6.232)	9.82 (7.975)	13.02 (8.240)	
Median	15.96	10.14	10.25	12.10	
Min, Max	1.8, 29.7	0.0, 24.5	0.0, 18.8	3.3, 28.6	
C4D1 CFB					
n	64	123	4	10	
LS Mean (StdErr) [2]	-1.95 (0.645)	-4.61 (0.498)	0.66 (4.698)	-0.53 (3.597)	
95% CI [2]	-3.22, -0.68	-5.60, -3.63	-9.80, 11.13	-8.55, 7.48	
Difference (95% CI) in CFB [2]		-2.66 (-4.10, -1.23)		-1.20 (-9.89, 7.50)	
p-value [3]		<0.001		0.766	

Skin Domain Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	63	127	4	10	
Mean (StdDev)	15.23 (7.792)	10.08 (5.950)	8.83 (6.803)	12.81 (8.800)	
Median	16.07	9.23	9.89	9.55	
Min, Max	1.4, 30.0	0.1, 25.2	0.0, 15.5	2.9, 28.5	
C5D1 CFB					
n	63	125	4	10	
LS Mean (StdErr) [2]	-2.01 (0.696)	-5.21 (0.526)	1.22 (4.993)	0.45 (3.823)	
95% CI [2]	-3.38, -0.63	-6.25, -4.17	-9.91, 12.34	-8.07, 8.97	
Difference (95% CI) in CFB [2]		-3.20 (-4.75, -1.66)		-0.77 (-10.01, 8.47)	
p-value [3]		<0.0001		0.857	

Skin Domain Score					
	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	62	126	4	10	
Mean (StdDev)	15.13 (7.720)	9.79 (6.133)	8.66 (6.413)	11.61 (8.772)	
Median	15.83	9.04	10.32	8.36	
Min, Max	1.4, 30.0	0.0, 29.4	0.0, 14.0	2.4, 30.0	
C6D1 CFB					
n	62	124	4	10	
LS Mean (StdErr) [2]	-2.08 (0.770)	-5.41 (0.581)	1.53 (4.120)	-0.21 (3.155)	
95% CI [2]	-3.60, -0.56	-6.56, -4.27	-7.65, 10.72	-7.24, 6.82	
Difference (95% CI) in CFB [2]		-3.33 (-5.05, -1.61)		-1.75 (-9.37, 5.88)	
p-value [3]		<0.001		0.621	

Skin Domain Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	63	123	3	10	
Mean (StdDev)	15.12 (7.531)	9.56 (6.103)	12.12 (4.631)	11.61 (9.159)	
Median	15.00	8.23	11.57	7.75	
Min, Max	1.2, 30.0	0.0, 28.9	7.8, 17.0	2.6, 30.0	
C7D1 CFB					
n	63	121	3	10	
LS Mean (StdErr) [2]	-2.07 (0.762)	-5.55 (0.584)	1.48 (5.486)	-0.64 (3.838)	
95% CI [2]	-3.57, -0.56	-6.70, -4.39	-10.93, 13.89	-9.32, 8.05	
Difference (95% CI) in CFB [2]		-3.48 (-5.18, -1.78)		-2.12 (-12.36, 8.12)	
Hedges'G (95% CI) in CFB		-0.55 (-0.87, -0.24)		-0.17 (-1.66, 1.24)	
p-value [3]		<0.0001		0.651	
					0.563

Neurocognitive Symptom Cluster					
	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	67	129	4	10	
Mean (StdDev)	12.65 (7.075)	12.93 (6.704)	13.64 (5.529)	14.40 (7.943)	
Median	11.00	12.50	12.61	14.46	
Min, Max	0.4, 29.1	0.0, 28.6	8.1, 21.3	2.4, 29.6	

Neurocognitive Symptom Cluster					
	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	67	127	4	10	
Mean (StdDev)	11.37 (6.893)	11.16 (6.496)	12.38 (3.249)	13.09 (8.808)	
Median	9.50	10.21	11.25	11.46	
Min, Max	0.2, 27.4	0.0, 28.1	9.9, 17.1	3.0, 30.0	
C2D1 CFB					
n	67	125	4	10	
LS Mean (StdErr) [2]	-1.19 (0.397)	-1.81 (0.313)	-0.11 (2.461)	-0.57 (1.885)	
95% CI [2]	-1.97, -0.41	-2.43, -1.19	-5.59, 5.37	-4.77, 3.63	
Difference (95% CI) in CFB [2]		-0.62 (-1.51, 0.27)		-0.46 (-5.02, 4.09)	
p-value [3]		0.170		0.825	

Neurocognitive Symptom Cluster

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	67	125	4	10	
Mean (StdDev)	10.39 (6.779)	10.17 (6.387)	12.02 (2.573)	12.16 (9.256)	
Median	8.89	9.08	12.39	10.46	
Min, Max	0.1, 27.3	0.0, 27.1	8.6, 14.7	1.5, 30.0	
C3D1 CFB					
n	67	123	4	10	
LS Mean (StdErr) [2]	-2.09 (0.494)	-2.76 (0.390)	0.50 (3.345)	-0.59 (2.561)	
95% CI [2]	-3.07, -1.12	-3.52, -1.99	-6.95, 7.96	-6.30, 5.11	
Difference (95% CI) in CFB [2]		-0.66 (-1.78, 0.45)		-1.10 (-7.28, 5.09)	
p-value [3]		0.240		0.702	

Neurocognitive Symptom Cluster	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	64	125	4	10	
Mean (StdDev)	10.39 (6.811)	9.67 (6.473)	11.71 (1.713)	12.18 (9.444)	
Median	8.93	8.45	11.93	11.18	
Min, Max	0.0, 25.6	0.0, 26.6	9.6, 13.4	0.7, 29.9	
C4D1 CFB					
n	64	123	4	10	
LS Mean (StdErr) [2]	-2.21 (0.587)	-3.35 (0.453)	0.24 (3.656)	-0.49 (2.799)	
95% CI [2]	-3.37, -1.05	-4.24, -2.46	-7.90, 8.39	-6.72, 5.75	
Difference (95% CI) in CFB [2]		-1.14 (-2.45, 0.16)		-0.73 (-7.49, 6.03)	
p-value [3]		0.086		0.815	

Neurocognitive Symptom Cluster

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	63	127	4	10	
Mean (StdDev)	10.19 (6.885)	9.35 (6.256)	11.27 (3.849)	12.89 (10.396)	
Median	8.86	8.00	13.15	12.45	
Min, Max	0.0, 26.2	0.0, 25.8	5.5, 13.3	0.5, 30.0	
C5D1 CFB					
n	63	125	4	10	
LS Mean (StdErr) [2]	-2.31 (0.582)	-3.52 (0.440)	2.22 (4.434)	1.68 (3.395)	
95% CI [2]	-3.45, -1.16	-4.39, -2.66	-7.66, 12.10	-5.89, 9.24	
Difference (95% CI) in CFB [2]		-1.22 (-2.51, 0.07)		-0.54 (-8.75, 7.66)	
p-value [3]		0.065		0.886	

Neurocognitive Symptom Cluster					
	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	62	126	4	10	
Mean (StdDev)	9.66 (6.569)	8.78 (6.316)	12.09 (2.367)	11.47 (10.424)	
Median	8.12	7.55	12.39	8.04	
Min, Max	0.0, 25.0	0.0, 29.6	9.0, 14.6	0.1, 30.0	
C6D1 CFB					
n	62	124	4	10	
LS Mean (StdErr) [2]	-2.70 (0.623)	-4.05 (0.470)	3.04 (3.665)	0.58 (2.806)	
95% CI [2]	-3.93, -1.47	-4.97, -3.12	-5.12, 11.21	-5.67, 6.84	
Difference (95% CI) in CFB [2]		-1.35 (-2.74, 0.04)		-2.46 (-9.24, 4.32)	
p-value [3]		0.057		0.438	

Neurocognitive Symptom Cluster	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	63	123	3	10	
Mean (StdDev)	9.79 (6.712)	8.70 (6.345)	13.00 (0.311)	11.45 (10.200)	
Median	7.64	7.82	12.86	9.18	
Min, Max	0.0, 23.4	0.0, 29.0	12.8, 13.4	0.7, 30.0	
C7D1 CFB					
n	63	121	3	10	
LS Mean (StdErr) [2]	-2.65 (0.634)	-4.04 (0.486)	3.03 (4.572)	0.19 (3.198)	
95% CI [2]	-3.90, -1.40	-5.00, -3.08	-7.31, 13.37	-7.04, 7.43	
Difference (95% CI) in CFB [2]		-1.39 (-2.81, 0.03)		-2.84 (-11.37, 5.70)	
Hedges'G (95% CI) in CFB		-0.26 (-0.58, 0.04)		-0.27 (-1.79, 1.12)	
p-value [3]		0.055		0.471	
					0.877

Gastrointestinal Domain Score					
	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	67	129	
Mean (StdDev)	6.66 (8.048)	13.21 (6.683)	10.64 (6.773)	9.44 (6.107)	
Median	3.61	12.75	9.92	8.31	
Min, Max	0.9, 18.6	2.9, 26.3	0.0, 28.0	0.0, 26.8	

Gastrointestinal Domain Score					
	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	67	127	
Mean (StdDev)	5.98 (7.370)	11.56 (6.134)	8.62 (6.334)	7.73 (5.738)	
Median	3.43	12.07	7.43	6.57	
Min, Max	0.4, 16.6	1.0, 19.9	0.0, 26.4	0.0, 24.0	
C2D1 CFB					
n	4	10	67	125	
LS Mean (StdErr) [2]	0.15 (1.934)	0.15 (1.934)	-1.80 (0.372)	-1.62 (0.292)	
95% CI [2]	-4.16, 4.46	-4.16, 4.46	-2.53, -1.06	-2.20, -1.04	
Difference (95% CI) in CFB [2]		0.00 (-5.48, 5.48)		0.18 (-0.65, 1.00)	
p-value [3]		>0.999		0.674	

Gastrointestinal Domain Score					
	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	8	67	127	
Mean (StdDev)	4.44 (5.493)	8.74 (5.299)	8.02 (6.341)	7.06 (5.611)	
Median	2.56	7.11	7.00	6.21	
Min, Max	0.1, 12.5	2.7, 17.9	0.0, 23.9	0.0, 24.0	
C3D1 CFB					
n	4	8	67	125	
LS Mean (StdErr) [2]	-2.51 (1.919)	-3.36 (1.919)	-2.31 (0.492)	-2.25 (0.386)	
95% CI [2]	-6.94, 1.92	-7.79, 1.06	-3.28, -1.34	-3.02, -1.49	
Difference (95% CI) in CFB [2]		-0.85 (-6.52, 4.81)		0.06 (-1.03, 1.15)	
p-value [3]		0.737		0.913	

Gastrointestinal Domain Score					
	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	4	9	64	126	
Mean (StdDev)	4.57 (7.243)	8.08 (5.242)	8.23 (6.172)	6.44 (5.686)	
Median	1.45	7.50	7.25	5.36	
Min, Max	0.0, 15.4	0.1, 19.2	0.0, 23.5	0.0, 24.8	
C4D1 CFB					
n	4	9	64	124	
LS Mean (StdErr) [2]	-2.79 (2.245)	-5.73 (2.245)	-2.36 (0.569)	-2.87 (0.437)	
95% CI [2]	-7.87, 2.29	-10.80, -0.65	-3.48, -1.23	-3.73, -2.01	
Difference (95% CI) in CFB [2]		-2.94 (-9.41, 3.54)		-0.51 (-1.77, 0.74)	
p-value [3]		0.331		0.420	

Gastrointestinal Domain Score					
	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	9	63	128	
Mean (StdDev)	4.18 (5.721)	6.61 (4.599)	8.39 (5.948)	6.35 (5.880)	
Median	2.05	6.38	7.50	4.89	
Min, Max	0.0, 12.6	0.0, 16.2	0.0, 23.3	0.0, 25.0	
C5D1 CFB					
n	4	9	63	126	
LS Mean (StdErr) [2]	-3.09 (2.294)	-6.54 (2.294)	-2.24 (0.617)	-2.96 (0.465)	
95% CI [2]	-8.28, 2.10	-11.73, -1.35	-3.46, -1.03	-3.88, -2.05	
Difference (95% CI) in CFB [2]		-3.45 (-10.07, 3.17)		-0.72 (-2.08, 0.63)	
p-value [3]		0.268		0.295	

Gastrointestinal Domain Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	62	127	
Mean (StdDev)	4.08 (6.333)	6.22 (4.623)	7.29 (5.883)	5.85 (5.644)	
Median	1.25	6.21	5.54	4.33	
Min, Max	0.3, 13.5	0.0, 16.6	0.0, 20.8	0.0, 25.5	
C6D1 CFB					
n	4	9	62	125	
LS Mean (StdErr) [2]	-3.63 (2.484)	-7.81 (2.484)	-2.91 (0.603)	-3.29 (0.454)	
95% CI [2]	-9.25, 1.99	-13.43, -2.19	-4.10, -1.72	-4.18, -2.39	
Difference (95% CI) in CFB [2]		-4.19 (-11.35, 2.98)		-0.38 (-1.71, 0.96)	
p-value [3]		0.219		0.579	

Gastrointestinal Domain Score					
	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	9	62	124	
Mean (StdDev)	4.59 (5.211)	7.04 (5.388)	7.55 (6.289)	5.84 (5.560)	
Median	3.18	5.43	6.04	4.51	
Min, Max	0.3, 11.7	0.0, 18.1	0.0, 22.9	0.0, 26.4	
C7D1 CFB					
n	4	9	62	122	
LS Mean (StdErr) [2]	-2.86 (2.981)	-6.94 (2.981)	-2.73 (0.632)	-3.27 (0.480)	
95% CI [2]	-9.60, 3.89	-13.68, -0.20	-3.98, -1.49	-4.22, -2.32	
Difference (95% CI) in CFB [2]		-4.08 (-12.68, 4.51)		-0.53 (-1.93, 0.87)	
Hedges'G (95% CI) in CFB		-0.46 (-1.91, 0.78)		-0.10 (-0.41, 0.20)	
p-value [3]		0.311		0.454	
					0.324

Skin Domain Score					
	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	67	129	
Mean (StdDev)	18.16 (8.488)	19.53 (8.401)	17.14 (7.624)	15.19 (6.955)	
Median	19.43	20.46	17.85	14.85	
Min, Max	6.8, 27.0	3.3, 29.6	0.0, 30.0	0.0, 30.0	

Skin Domain Score					
	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	67	127	
Mean (StdDev)	17.98 (7.879)	16.57 (6.640)	15.50 (7.472)	12.64 (6.315)	
Median	18.82	17.43	16.14	12.50	
Min, Max	7.8, 26.5	3.3, 25.9	0.0, 29.8	0.0, 28.5	
C2D1 CFB					
n	4	10	67	125	
LS Mean (StdErr) [2]	-0.38 (1.961)	-2.53 (1.961)	-1.59 (0.480)	-2.65 (0.377)	
95% CI [2]	-4.75, 3.99	-6.90, 1.84	-2.53, -0.64	-3.39, -1.91	
Difference (95% CI) in CFB [2]		-2.14 (-7.70, 3.41)		-1.06 (-2.13, 0.00)	
p-value [3]		0.410		0.051	

Skin Domain Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	8	67	127	
Mean (StdDev)	16.20 (7.234)	14.25 (6.533)	15.04 (7.729)	11.28 (6.254)	
Median	18.89	12.07	14.86	10.30	
Min, Max	5.8, 21.2	4.4, 24.1	0.0, 29.4	0.0, 28.1	
C3D1 CFB					
n	4	8	67	125	
LS Mean (StdErr) [2]	-1.37 (3.213)	-4.80 (3.213)	-1.80 (0.588)	-3.79 (0.462)	
95% CI [2]	-8.78, 6.04	-12.21, 2.61	-2.96, -0.64	-4.70, -2.88	
Difference (95% CI) in CFB [2]		-3.43 (-12.90, 6.05)		-1.99 (-3.29, -0.68)	
p-value [3]		0.429		0.003	

Skin Domain Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	4	9	64	126	
Mean (StdDev)	16.19 (7.844)	11.99 (6.210)	14.82 (7.792)	10.74 (6.424)	
Median	18.76	10.93	14.92	10.15	
Min, Max	5.1, 22.2	3.9, 24.0	0.0, 29.7	0.0, 28.6	
C4D1 CFB					
n	4	9	64	124	
LS Mean (StdErr) [2]	-1.61 (3.506)	-6.23 (3.506)	-1.95 (0.650)	-4.32 (0.500)	
95% CI [2]	-9.54, 6.32	-14.16, 1.70	-3.23, -0.66	-5.30, -3.33	
Difference (95% CI) in CFB [2]		-4.62 (-14.73, 5.49)		-2.37 (-3.80, -0.94)	
p-value [3]		0.328		0.001	

Skin Domain Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	9	63	128	
Mean (StdDev)	15.26 (8.863)	11.28 (6.515)	14.82 (7.850)	10.21 (6.198)	
Median	17.44	10.36	15.54	9.24	
Min, Max	3.4, 22.8	4.4, 23.2	0.0, 30.0	0.1, 28.5	
C5D1 CFB					
n	4	9	63	126	
LS Mean (StdErr) [2]	-3.58 (3.849)	-8.30 (3.849)	-1.93 (0.701)	-4.80 (0.528)	
95% CI [2]	-12.28, 5.13	-17.01, 0.41	-3.31, -0.55	-5.84, -3.76	
Difference (95% CI) in CFB [2]		-4.72 (-15.82, 6.38)		-2.87 (-4.41, -1.33)	
p-value [3]		0.361		<0.001	

Skin Domain Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	62	127	
Mean (StdDev)	13.87 (8.943)	10.38 (5.729)	14.80 (7.760)	9.89 (6.400)	
Median	16.54	8.71	15.34	8.86	
Min, Max	1.7, 20.7	3.8, 20.5	0.0, 30.0	0.0, 30.0	
C6D1 CFB					
n	4	9	62	125	
LS Mean (StdErr) [2]	-4.97 (3.795)	-9.39 (3.795)	-1.89 (0.763)	-5.00 (0.574)	
95% CI [2]	-13.56, 3.61	-17.98, -0.80	-3.40, -0.39	-6.13, -3.87	
Difference (95% CI) in CFB [2]		-4.42 (-15.36, 6.53)		-3.11 (-4.79, -1.42)	
p-value [3]		0.385		<0.001	

Skin Domain Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	9	62	124	
Mean (StdDev)	14.83 (8.671)	10.08 (5.903)	14.99 (7.421)	9.68 (6.413)	
Median	17.57	9.21	14.83	8.00	
Min, Max	2.7, 21.5	3.5, 20.6	1.2, 30.0	0.0, 30.0	
C7D1 CFB					
n	4	9	62	122	
LS Mean (StdErr) [2]	-3.96 (3.806)	-9.57 (3.806)	-1.94 (0.768)	-5.13 (0.584)	
95% CI [2]	-12.57, 4.65	-18.18, -0.96	-3.46, -0.43	-6.28, -3.98	
Difference (95% CI) in CFB [2]		-5.61 (-16.59, 5.37)		-3.18 (-4.88, -1.48)	
Hedges'G (95% CI) in CFB		-0.50 (-1.95, 0.74)		-0.50 (-0.82, -0.20)	
p-value [3]		0.277		<0.001	
					0.516

Neurocognitive Symptom Cluster

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	67	129	
Mean (StdDev)	10.23 (9.591)	15.60 (7.022)	12.86 (6.851)	12.84 (6.747)	
Median	10.32	15.61	11.29	12.46	
Min, Max	1.6, 18.6	2.2, 26.0	0.4, 29.1	0.0, 29.6	

Neurocognitive Symptom Cluster					
	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	67	127	
Mean (StdDev)	7.93 (8.631)	14.41 (6.743)	11.64 (6.624)	11.05 (6.629)	
Median	6.50	15.18	9.86	10.07	
Min, Max	0.4, 18.3	1.9, 25.9	0.2, 27.4	0.0, 30.0	
C2D1 CFB					
n	4	10	67	125	
LS Mean (StdErr) [2]	-3.04 (0.841)	-1.92 (0.841)	-1.07 (0.411)	-1.77 (0.322)	
95% CI [2]	-4.92, -1.17	-3.80, -0.05	-1.88, -0.26	-2.41, -1.14	
Difference (95% CI) in CFB [2]		1.12 (-1.27, 3.50)		-0.70 (-1.62, 0.21)	
p-value [3]		0.321		0.129	

Neurocognitive Symptom Cluster

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	8	67	127	
Mean (StdDev)	8.38 (9.299)	14.21 (6.741)	10.61 (6.495)	10.07 (6.558)	
Median	7.50	15.89	9.07	9.00	
Min, Max	0.3, 18.2	3.5, 25.0	0.1, 27.3	0.0, 30.0	
C3D1 CFB					
n	4	8	67	125	
LS Mean (StdErr) [2]	-2.51 (1.488)	-2.54 (1.488)	-2.03 (0.512)	-2.73 (0.402)	
95% CI [2]	-5.94, 0.92	-5.97, 0.89	-3.04, -1.02	-3.52, -1.94	
Difference (95% CI) in CFB [2]		-0.03 (-4.42, 4.36)		-0.70 (-1.83, 0.44)	
p-value [3]		0.987		0.228	

Neurocognitive Symptom Cluster	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	4	9	64	126	
Mean (StdDev)	6.70 (8.608)	11.67 (6.574)	10.70 (6.492)	9.72 (6.741)	
Median	4.32	9.29	9.79	8.30	
Min, Max	0.0, 18.2	2.1, 24.6	0.6, 25.6	0.0, 29.9	
C4D1 CFB					
n	4	9	64	124	
LS Mean (StdErr) [2]	-5.33 (1.869)	-5.87 (1.869)	-1.99 (0.600)	-3.10 (0.461)	
95% CI [2]	-9.55, -1.10	-10.10, -1.65	-3.17, -0.80	-4.01, -2.19	
Difference (95% CI) in CFB [2]		-0.55 (-5.94, 4.84)		-1.12 (-2.44, 0.20)	
p-value [3]		0.823		0.097	

Neurocognitive Symptom Cluster					
	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	9	63	128	
Mean (StdDev)	6.17 (8.337)	10.39 (6.311)	10.52 (6.610)	9.55 (6.697)	
Median	3.50	8.46	9.64	7.93	
Min, Max	0.0, 17.7	1.8, 24.5	0.5, 26.2	0.0, 30.0	
C5D1 CFB					
n	4	9	63	126	
LS Mean (StdErr) [2]	-6.23 (1.641)	-7.43 (1.641)	-2.05 (0.614)	-3.09 (0.463)	
95% CI [2]	-9.95, -2.52	-11.14, -3.72	-3.26, -0.84	-4.00, -2.17	
Difference (95% CI) in CFB [2]		-1.20 (-5.93, 3.53)		-1.03 (-2.38, 0.32)	
p-value [3]		0.581		0.134	

Neurocognitive Symptom Cluster					
	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	62	127	
Mean (StdDev)	6.02 (8.414)	9.49 (6.433)	10.05 (6.270)	8.94 (6.725)	
Median	3.11	8.71	8.75	7.29	
Min, Max	0.0, 17.8	1.6, 23.4	0.1, 25.0	0.0, 30.0	
C6D1 CFB					
n	4	9	62	125	
LS Mean (StdErr) [2]	-6.85 (2.161)	-8.89 (2.161)	-2.34 (0.630)	-3.62 (0.474)	
95% CI [2]	-11.74, -1.97	-13.78, -4.01	-3.59, -1.10	-4.56, -2.69	
Difference (95% CI) in CFB [2]		-2.04 (-8.27, 4.19)		-1.28 (-2.68, 0.11)	
p-value [3]		0.478		0.071	

Neurocognitive Symptom Cluster					
	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	9	62	124	
Mean (StdDev)	5.95 (7.973)	9.96 (6.870)	10.20 (6.483)	8.83 (6.705)	
Median	3.46	8.27	8.90	7.73	
Min, Max	0.0, 16.9	1.9, 24.7	0.0, 23.4	0.0, 30.0	
C7D1 CFB					
n	4	9	62	122	
LS Mean (StdErr) [2]	-6.61 (2.488)	-7.64 (2.488)	-2.27 (0.648)	-3.67 (0.493)	
95% CI [2]	-12.24, -0.98	-13.27, -2.01	-3.55, -0.99	-4.65, -2.70	
Difference (95% CI) in CFB [2]		-1.03 (-8.21, 6.14)		-1.41 (-2.84, 0.03)	
Hedges'G (95% CI) in CFB		-0.14 (-1.50, 1.15)		-0.26 (-0.57, 0.04)	
p-value [3]		0.752		0.055	
					0.694

Bone Pain Severity					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	130	11	9	
Mean (StdDev)	5.72 (2.322)	5.27 (2.593)	3.65 (2.432)	5.23 (2.759)	
Median	5.79	5.61	3.43	5.54	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 7.0	0.0, 8.4	

Bone Pain Severity

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	60	128	11	9	
Mean (StdDev)	4.99 (2.545)	4.56 (2.712)	3.82 (2.574)	4.38 (2.701)	
Median	5.03	4.14	3.50	4.46	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 7.9	0.0, 7.7	
C2D1 CFB					
n	60	126	11	9	
LS Mean (StdErr) [2]	-0.67 (0.177)	-0.70 (0.132)	0.16 (0.367)	-0.78 (0.466)	
95% CI [2]	-1.02, -0.32	-0.96, -0.44	-0.62, 0.94	-1.77, 0.21	
Difference (95% CI) in CFB [2]		-0.03 (-0.43, 0.36)		-0.94 (-1.67, -0.22)	
p-value [3]		0.864		0.014	

Bone Pain Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	60	126	11	9	
Mean (StdDev)	4.94 (2.601)	4.33 (2.762)	3.17 (2.690)	3.83 (2.673)	
Median	5.31	3.89	2.86	4.43	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 6.9	0.0, 8.2	
C3D1 CFB					
n	60	124	11	9	
LS Mean (StdErr) [2]	-0.75 (0.209)	-0.94 (0.155)	-0.13 (0.669)	-0.73 (0.848)	
95% CI [2]	-1.16, -0.33	-1.25, -0.63	-1.54, 1.29	-2.53, 1.06	
Difference (95% CI) in CFB [2]		-0.19 (-0.66, 0.27)		-0.61 (-1.93, 0.71)	
p-value [3]		0.407		0.344	

Bone Pain Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	58	126	10	9	
Mean (StdDev)	4.97 (2.668)	4.36 (2.837)	3.07 (2.710)	3.21 (2.539)	
Median	4.68	4.00	2.39	2.14	
Min, Max	0.0, 9.8	0.0, 10.0	0.0, 6.8	0.0, 8.2	
C4D1 CFB					
n	58	124	10	9	
LS Mean (StdErr) [2]	-0.68 (0.245)	-0.85 (0.179)	-0.24 (0.894)	-1.22 (1.125)	
95% CI [2]	-1.16, -0.19	-1.20, -0.49	-2.14, 1.67	-3.61, 1.18	
Difference (95% CI) in CFB [2]		-0.17 (-0.71, 0.37)		-0.98 (-2.76, 0.81)	
p-value [3]		0.535		0.262	

Bone Pain Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	58	128	9	9	
Mean (StdDev)	4.98 (2.635)	4.14 (2.824)	2.87 (2.759)	2.81 (2.738)	
Median	4.79	4.01	2.29	1.79	
Min, Max	0.0, 9.8	0.0, 10.0	0.0, 7.1	0.0, 8.6	
C5D1 CFB					
n	58	126	9	9	
LS Mean (StdErr) [2]	-0.60 (0.255)	-0.97 (0.184)	-0.22 (1.182)	-1.62 (1.474)	
95% CI [2]	-1.10, -0.10	-1.33, -0.60	-2.76, 2.31	-4.78, 1.54	
Difference (95% CI) in CFB [2]		-0.37 (-0.93, 0.19)		-1.40 (-3.79, 0.99)	
p-value [3]		0.198		0.231	

Bone Pain Severity

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	56	127	10	9	
Mean (StdDev)	4.92 (2.665)	4.01 (2.737)	3.19 (2.656)	2.60 (2.697)	
Median	5.04	3.71	3.18	2.00	
Min, Max	0.0, 9.6	0.0, 10.0	0.0, 7.0	0.0, 8.7	
C6D1 CFB					
n	56	125	10	9	
LS Mean (StdErr) [2]	-0.50 (0.266)	-1.05 (0.190)	-0.17 (1.153)	-1.90 (1.452)	
95% CI [2]	-1.03, 0.02	-1.42, -0.67	-2.63, 2.29	-5.00, 1.19	
Difference (95% CI) in CFB [2]		-0.55 (-1.13, 0.04)		-1.73 (-4.04, 0.57)	
p-value [3]		0.068		0.130	

Bone Pain Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	56	124	10	9	
Mean (StdDev)	4.83 (2.682)	3.94 (2.767)	3.39 (2.584)	2.67 (2.796)	
Median	5.25	3.52	4.11	2.29	
Min, Max	0.0, 9.4	0.0, 10.0	0.0, 6.9	0.0, 8.9	
C7D1 CFB					
n	56	122	10	9	
LS Mean (StdErr) [2]	-0.68 (0.274)	-1.11 (0.198)	0.13 (1.145)	-1.37 (1.442)	
95% CI [2]	-1.22, -0.14	-1.50, -0.72	-2.31, 2.57	-4.45, 1.70	
Difference (95% CI) in CFB [2]		-0.42 (-1.03, 0.18)		-1.50 (-3.79, 0.79)	
Hedges'G (95% CI) in CFB		-0.20 (-0.52, 0.12)		-0.36 (-1.39, 0.57)	
p-value [3]		0.169		0.182	
					0.114

Abdominal Pain Severity

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	130	11	9	
Mean (StdDev)	4.31 (2.441)	3.90 (2.243)	2.20 (1.898)	3.52 (2.789)	
Median	4.23	3.77	1.86	4.00	
Min, Max	0.0, 9.6	0.0, 9.8	0.0, 5.7	0.0, 6.9	

Abdominal Pain Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	60	128	11	9	
Mean (StdDev)	3.48 (2.229)	3.19 (2.176)	1.92 (1.611)	2.78 (2.208)	
Median	3.57	2.84	1.36	3.50	
Min, Max	0.0, 8.9	0.0, 9.4	0.0, 4.6	0.0, 5.6	
C2D1 CFB					
n	60	126	11	9	
LS Mean (StdErr) [2]	-0.73 (0.161)	-0.66 (0.119)	-0.22 (0.435)	-0.59 (0.552)	
95% CI [2]	-1.04, -0.41	-0.89, -0.42	-1.14, 0.70	-1.76, 0.58	
Difference (95% CI) in CFB [2]		0.07 (-0.29, 0.42)		-0.38 (-1.24, 0.48)	
p-value [3]		0.701		0.369	

Abdominal Pain Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	60	126	11	9	
Mean (StdDev)	3.23 (2.265)	2.85 (2.171)	2.10 (1.863)	1.76 (2.092)	
Median	3.00	2.46	1.64	1.29	
Min, Max	0.0, 8.4	0.0, 8.3	0.0, 5.4	0.0, 5.5	
C3D1 CFB					
n	60	124	11	9	
LS Mean (StdErr) [2]	-0.93 (0.200)	-0.96 (0.149)	-0.25 (0.669)	-1.81 (0.848)	
95% CI [2]	-1.32, -0.54	-1.25, -0.67	-1.67, 1.17	-3.61, -0.01	
Difference (95% CI) in CFB [2]		-0.03 (-0.47, 0.41)		-1.56 (-2.88, -0.23)	
p-value [3]		0.898		0.024	

Abdominal Pain Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	58	126	10	9	
Mean (StdDev)	3.18 (2.261)	2.58 (2.192)	2.08 (1.514)	1.80 (1.975)	
Median	3.15	2.23	2.83	0.92	
Min, Max	0.0, 7.9	0.0, 9.1	0.0, 3.7	0.0, 5.0	
C4D1 CFB					
n	58	124	10	9	
LS Mean (StdErr) [2]	-1.02 (0.239)	-1.23 (0.175)	-0.55 (0.807)	-2.09 (1.016)	
95% CI [2]	-1.49, -0.55	-1.57, -0.88	-2.27, 1.17	-4.26, 0.07	
Difference (95% CI) in CFB [2]		-0.20 (-0.73, 0.32)		-1.54 (-3.15, 0.07)	
p-value [3]		0.443		0.060	

Abdominal Pain Severity

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	58	128	9	9	
Mean (StdDev)	3.19 (2.253)	2.49 (2.281)	2.55 (1.938)	1.47 (1.845)	
Median	2.85	1.93	3.00	0.71	
Min, Max	0.0, 8.1	0.0, 9.4	0.0, 5.6	0.0, 5.2	
C5D1 CFB					
n	58	126	9	9	
LS Mean (StdErr) [2]	-0.99 (0.256)	-1.31 (0.185)	0.11 (1.071)	-2.01 (1.336)	
95% CI [2]	-1.49, -0.48	-1.67, -0.94	-2.19, 2.41	-4.88, 0.85	
Difference (95% CI) in CFB [2]		-0.32 (-0.88, 0.24)		-2.12 (-4.29, 0.05)	
p-value [3]		0.265		0.054	

Abdominal Pain Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	56	127	10	9	
Mean (StdDev)	2.75 (2.157)	2.31 (2.239)	1.72 (1.388)	1.75 (2.000)	
Median	2.52	1.77	1.86	0.71	
Min, Max	0.0, 7.1	0.0, 9.6	0.0, 3.9	0.0, 5.4	
C6D1 CFB					
n	56	125	10	9	
LS Mean (StdErr) [2]	-1.25 (0.270)	-1.44 (0.193)	-0.43 (0.825)	-1.45 (1.039)	
95% CI [2]	-1.78, -0.71	-1.82, -1.06	-2.18, 1.33	-3.67, 0.76	
Difference (95% CI) in CFB [2]		-0.19 (-0.78, 0.41)		-1.03 (-2.67, 0.62)	
p-value [3]		0.531		0.205	

Abdominal Pain Severity

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	56	124	10	9	
Mean (StdDev)	2.93 (2.345)	2.36 (2.194)	1.90 (1.839)	1.68 (2.072)	
Median	2.39	1.92	1.89	0.29	
Min, Max	0.0, 8.3	0.0, 9.4	0.0, 4.9	0.0, 5.1	
C7D1 CFB					
n	56	122	10	9	
LS Mean (StdErr) [2]	-1.14 (0.264)	-1.39 (0.190)	-0.82 (0.800)	-2.43 (1.007)	
95% CI [2]	-1.66, -0.62	-1.77, -1.01	-2.52, 0.89	-4.57, -0.28	
Difference (95% CI) in CFB [2]		-0.25 (-0.83, 0.33)		-1.61 (-3.21, -0.01)	
Hedges'G (95% CI) in CFB		-0.12 (-0.44, 0.20)		-0.55 (-1.62, 0.36)	
p-value [3]		0.395		0.049	
					0.263

Nausea Severity					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	130	11	9	
Mean (StdDev)	3.60 (2.506)	2.93 (2.525)	2.05 (2.136)	3.11 (3.001)	
Median	3.36	2.50	1.15	1.93	
Min, Max	0.0, 8.9	0.0, 9.0	0.0, 6.4	0.0, 6.7	

Nausea Severity

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	60	128	11	9	
Mean (StdDev)	3.11 (2.433)	2.57 (2.333)	1.47 (1.332)	2.30 (2.400)	
Median	2.77	2.22	1.62	1.77	
Min, Max	0.0, 8.3	0.0, 8.8	0.0, 4.2	0.0, 6.2	
C2D1 CFB					
n	60	126	11	9	
LS Mean (StdErr) [2]	-0.36 (0.164)	-0.28 (0.122)	-2.36 (0.712)	-2.74 (0.904)	
95% CI [2]	-0.69, -0.04	-0.52, -0.04	-3.87, -0.85	-4.65, -0.82	
Difference (95% CI) in CFB [2]		0.08 (-0.28, 0.45)		-0.38 (-1.79, 1.03)	
p-value [3]		0.646		0.577	

Nausea Severity

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	60	126	11	9	
Mean (StdDev)	2.72 (2.366)	2.31 (2.252)	1.49 (1.617)	2.10 (2.278)	
Median	2.19	1.74	1.08	1.07	
Min, Max	0.0, 7.7	0.0, 8.9	0.0, 4.9	0.0, 5.9	
C3D1 CFB					
n	60	124	11	9	
LS Mean (StdErr) [2]	-0.76 (0.199)	-0.55 (0.148)	-2.65 (0.800)	-3.27 (1.015)	
95% CI [2]	-1.15, -0.37	-0.85, -0.26	-4.35, -0.95	-5.42, -1.12	
Difference (95% CI) in CFB [2]		0.21 (-0.24, 0.65)		-0.62 (-2.20, 0.96)	
p-value [3]		0.360		0.417	

Nausea Severity

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	58	126	10	9	
Mean (StdDev)	2.73 (2.341)	2.05 (2.226)	1.81 (1.383)	1.49 (2.071)	
Median	1.93	1.36	2.04	0.36	
Min, Max	0.0, 7.4	0.0, 9.2	0.0, 4.0	0.0, 5.5	
C4D1 CFB					
n	58	124	10	9	
LS Mean (StdErr) [2]	-0.86 (0.231)	-0.88 (0.169)	-2.00 (0.771)	-3.32 (0.971)	
95% CI [2]	-1.31, -0.40	-1.22, -0.55	-3.64, -0.35	-5.39, -1.25	
Difference (95% CI) in CFB [2]		-0.03 (-0.53, 0.48)		-1.32 (-2.86, 0.22)	
p-value [3]		0.919		0.088	

Nausea Severity					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	58	128	9	9	
Mean (StdDev)	2.77 (2.315)	2.05 (2.231)	1.83 (1.396)	1.16 (1.827)	
Median	2.64	1.39	1.71	0.29	
Min, Max	0.0, 8.5	0.0, 8.9	0.0, 3.8	0.0, 5.4	
C5D1 CFB					
n	58	126	9	9	
LS Mean (StdErr) [2]	-0.79 (0.248)	-0.85 (0.179)	-2.33 (0.851)	-4.01 (1.061)	
95% CI [2]	-1.28, -0.30	-1.20, -0.50	-4.16, -0.51	-6.29, -1.74	
Difference (95% CI) in CFB [2]		-0.06 (-0.60, 0.49)		-1.68 (-3.40, 0.04)	
p-value [3]		0.831		0.055	

Nausea Severity

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	56	127	10	9	
Mean (StdDev)	2.48 (2.203)	1.81 (2.135)	1.36 (1.286)	1.38 (2.240)	
Median	2.21	1.36	1.04	0.07	
Min, Max	0.0, 7.9	0.0, 9.9	0.0, 3.5	0.0, 5.7	
C6D1 CFB					
n	56	125	10	9	
LS Mean (StdErr) [2]	-1.06 (0.251)	-1.07 (0.179)	-2.92 (0.776)	-3.93 (0.977)	
95% CI [2]	-1.55, -0.56	-1.43, -0.72	-4.57, -1.27	-6.01, -1.85	
Difference (95% CI) in CFB [2]		-0.02 (-0.57, 0.54)		-1.01 (-2.56, 0.54)	
p-value [3]		0.957		0.186	

Nausea Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	56	124	10	9	
Mean (StdDev)	2.56 (2.335)	1.88 (2.149)	1.57 (1.796)	1.20 (1.908)	
Median	1.93	1.26	0.59	0.14	
Min, Max	0.0, 7.7	0.0, 9.5	0.0, 4.6	0.0, 5.4	
C7D1 CFB					
n	56	122	10	9	
LS Mean (StdErr) [2]	-0.96 (0.270)	-0.98 (0.195)	-2.95 (0.857)	-4.56 (1.079)	
95% CI [2]	-1.50, -0.43	-1.37, -0.60	-4.78, -1.13	-6.86, -2.26	
Difference (95% CI) in CFB [2]		-0.02 (-0.62, 0.58)		-1.61 (-3.32, 0.10)	
Hedges'G (95% CI) in CFB		-0.01 (-0.33, 0.31)		-0.52 (-1.58, 0.40)	
p-value [3]		0.949		0.063	
					0.283

Spots Severity					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	130	11	9	
Mean (StdDev)	5.46 (3.106)	5.24 (3.047)	7.47 (2.854)	6.14 (2.890)	
Median	6.07	5.38	9.00	6.64	
Min, Max	0.0, 10.0	0.0, 10.0	2.2, 10.0	0.0, 9.3	

Spots Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	60	128	11	9	
Mean (StdDev)	5.05 (2.843)	4.45 (2.760)	7.25 (2.963)	4.32 (3.324)	
Median	5.42	4.47	8.71	5.00	
Min, Max	0.0, 10.0	0.0, 10.0	2.1, 10.0	0.0, 9.0	
C2D1 CFB					
n	60	126	11	9	
LS Mean (StdErr) [2]	-0.33 (0.164)	-0.78 (0.121)	-0.24 (0.902)	-2.02 (1.143)	
95% CI [2]	-0.65, -0.00	-1.01, -0.54	-2.15, 1.68	-4.45, 0.40	
Difference (95% CI) in CFB [2]		-0.45 (-0.81, -0.09)		-1.79 (-3.57, -0.00)	
p-value [3]		0.015		0.050	

Spots Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	60	126	11	9	
Mean (StdDev)	5.05 (2.898)	4.05 (2.626)	6.98 (3.065)	3.99 (3.010)	
Median	5.17	4.00	8.00	3.86	
Min, Max	0.0, 10.0	0.0, 9.8	1.1, 10.0	0.0, 8.4	
C3D1 CFB					
n	60	124	11	9	
LS Mean (StdErr) [2]	-0.21 (0.207)	-1.11 (0.154)	-0.83 (0.938)	-2.78 (1.189)	
95% CI [2]	-0.62, 0.20	-1.41, -0.81	-2.81, 1.16	-5.30, -0.26	
Difference (95% CI) in CFB [2]		-0.90 (-1.36, -0.44)		-1.96 (-3.81, -0.10)	
p-value [3]		<0.001		0.040	

Spots Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	58	126	10	9	
Mean (StdDev)	4.95 (2.924)	3.86 (2.606)	6.95 (3.089)	3.45 (3.108)	
Median	5.11	3.70	7.50	3.31	
Min, Max	0.0, 10.0	0.0, 9.4	1.9, 10.0	0.0, 8.2	
C4D1 CFB					
n	58	124	10	9	
LS Mean (StdErr) [2]	-0.23 (0.215)	-1.21 (0.157)	-0.37 (1.109)	-2.89 (1.397)	
95% CI [2]	-0.65, 0.20	-1.52, -0.90	-2.74, 1.99	-5.87, 0.08	
Difference (95% CI) in CFB [2]		-0.98 (-1.45, -0.51)		-2.52 (-4.73, -0.30)	
p-value [3]		<0.0001		0.028	

Spots Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	58	128	9	9	
Mean (StdDev)	4.78 (2.952)	3.66 (2.543)	7.32 (2.742)	3.30 (3.274)	
Median	5.04	3.18	8.00	2.38	
Min, Max	0.0, 10.0	0.0, 9.9	3.3, 10.0	0.0, 8.6	
C5D1 CFB					
n	58	126	9	9	
LS Mean (StdErr) [2]	-0.45 (0.232)	-1.44 (0.167)	-0.40 (1.221)	-3.37 (1.523)	
95% CI [2]	-0.91, 0.01	-1.77, -1.11	-3.02, 2.21	-6.64, -0.11	
Difference (95% CI) in CFB [2]		-0.99 (-1.50, -0.48)		-2.97 (-5.44, -0.50)	
p-value [3]		<0.001		0.022	

Spots Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	56	127	10	9	
Mean (StdDev)	4.94 (2.937)	3.50 (2.557)	6.61 (3.408)	3.20 (3.144)	
Median	5.00	3.17	7.36	2.57	
Min, Max	0.0, 10.0	0.0, 10.0	0.4, 10.0	0.0, 8.6	
C6D1 CFB					
n	56	125	10	9	
LS Mean (StdErr) [2]	-0.21 (0.276)	-1.49 (0.197)	-0.77 (1.202)	-3.28 (1.513)	
95% CI [2]	-0.76, 0.33	-1.88, -1.10	-3.33, 1.79	-6.51, -0.06	
Difference (95% CI) in CFB [2]		-1.28 (-1.88, -0.67)		-2.51 (-4.91, -0.11)	
p-value [3]		<0.0001		0.042	

Spots Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	56	124	10	9	
Mean (StdDev)	4.94 (2.916)	3.46 (2.646)	6.83 (2.957)	3.61 (3.055)	
Median	4.93	3.15	7.23	2.79	
Min, Max	0.0, 10.0	0.0, 10.0	2.4, 10.0	0.0, 8.4	
C7D1 CFB					
n	56	122	10	9	
LS Mean (StdErr) [2]	-0.35 (0.286)	-1.58 (0.206)	-0.53 (1.072)	-2.54 (1.350)	
95% CI [2]	-0.92, 0.21	-1.99, -1.17	-2.82, 1.75	-5.42, 0.34	
Difference (95% CI) in CFB [2]		-1.22 (-1.86, -0.59)		-2.01 (-4.15, 0.13)	
Hedges'G (95% CI) in CFB		-0.55 (-0.88, -0.23)		-0.52 (-1.58, 0.40)	
p-value [3]		<0.001		0.064	
					0.525

Itching Severity					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	130	11	9	
Mean (StdDev)	5.55 (2.791)	5.02 (2.787)	6.56 (2.756)	6.70 (2.712)	
Median	6.18	5.08	7.00	8.14	
Min, Max	0.0, 10.0	0.0, 10.0	1.9, 10.0	2.5, 9.6	

Itching Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	60	128	11	9	
Mean (StdDev)	4.95 (2.687)	4.04 (2.485)	5.76 (3.438)	4.92 (2.631)	
Median	5.44	4.07	6.36	5.07	
Min, Max	0.0, 10.0	0.0, 9.9	0.5, 9.8	1.6, 8.6	
C2D1 CFB					
n	60	126	11	9	
LS Mean (StdErr) [2]	-0.59 (0.216)	-1.06 (0.161)	-0.50 (0.869)	-1.91 (1.102)	
95% CI [2]	-1.02, -0.17	-1.38, -0.74	-2.34, 1.34	-4.25, 0.42	
Difference (95% CI) in CFB [2]		-0.46 (-0.94, 0.01)		-1.42 (-3.13, 0.30)	
p-value [3]		0.057		0.100	

Itching Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	60	126	11	9	
Mean (StdDev)	4.68 (2.782)	3.46 (2.464)	5.32 (3.080)	3.87 (2.930)	
Median	4.78	3.18	5.85	3.07	
Min, Max	0.0, 10.0	0.0, 9.7	0.0, 9.1	0.8, 8.9	
C3D1 CFB					
n	60	124	11	9	
LS Mean (StdErr) [2]	-0.74 (0.263)	-1.53 (0.196)	-1.02 (1.178)	-2.89 (1.494)	
95% CI [2]	-1.26, -0.22	-1.91, -1.14	-3.51, 1.48	-6.06, 0.27	
Difference (95% CI) in CFB [2]		-0.78 (-1.37, -0.20)		-1.88 (-4.20, 0.45)	
p-value [3]		0.009		0.107	

Itching Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	58	126	10	9	
Mean (StdDev)	4.55 (2.836)	3.25 (2.561)	5.42 (3.132)	3.60 (2.954)	
Median	4.93	3.07	6.47	1.86	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 9.1	1.1, 9.0	
C4D1 CFB					
n	58	124	10	9	
LS Mean (StdErr) [2]	-0.96 (0.309)	-1.79 (0.226)	-0.83 (1.495)	-2.58 (1.883)	
95% CI [2]	-1.57, -0.35	-2.24, -1.35	-4.02, 2.35	-6.59, 1.44	
Difference (95% CI) in CFB [2]		-0.83 (-1.51, -0.15)		-1.74 (-4.73, 1.24)	
p-value [3]		0.017		0.233	

Itching Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	58	128	9	9	
Mean (StdDev)	4.53 (2.741)	3.06 (2.491)	6.32 (2.586)	2.88 (3.136)	
Median	4.64	2.82	6.77	1.21	
Min, Max	0.0, 10.0	0.0, 10.0	2.2, 10.0	0.3, 9.0	
C5D1 CFB					
n	58	126	9	9	
LS Mean (StdErr) [2]	-0.92 (0.319)	-1.92 (0.231)	-0.53 (1.464)	-3.56 (1.826)	
95% CI [2]	-1.55, -0.29	-2.37, -1.46	-3.67, 2.60	-7.48, 0.35	
Difference (95% CI) in CFB [2]		-1.00 (-1.70, -0.29)		-3.03 (-5.99, -0.07)	
p-value [3]		0.006		0.046	

Itching Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	56	127	10	9	
Mean (StdDev)	4.53 (2.685)	3.01 (2.507)	5.74 (3.051)	2.91 (2.947)	
Median	4.55	2.71	6.21	2.07	
Min, Max	0.0, 10.0	0.0, 10.0	0.1, 10.0	0.3, 9.0	
C6D1 CFB					
n	56	125	10	9	
LS Mean (StdErr) [2]	-0.93 (0.333)	-2.00 (0.238)	-0.70 (1.428)	-3.49 (1.797)	
95% CI [2]	-1.58, -0.27	-2.47, -1.53	-3.74, 2.35	-7.32, 0.34	
Difference (95% CI) in CFB [2]		-1.07 (-1.81, -0.34)		-2.80 (-5.65, 0.05)	
p-value [3]		0.004		0.054	

Itching Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	56	124	10	9	
Mean (StdDev)	4.67 (2.606)	2.96 (2.472)	5.78 (2.821)	3.26 (3.165)	
Median	4.80	2.67	6.81	1.64	
Min, Max	0.0, 10.0	0.0, 10.0	1.8, 9.9	0.0, 9.0	
C7D1 CFB					
n	56	122	10	9	
LS Mean (StdErr) [2]	-0.89 (0.349)	-2.05 (0.252)	-0.36 (1.289)	-2.45 (1.623)	
95% CI [2]	-1.58, -0.20	-2.55, -1.56	-3.11, 2.39	-5.91, 1.01	
Difference (95% CI) in CFB [2]		-1.16 (-1.93, -0.39)		-2.09 (-4.66, 0.49)	
Hedges'G (95% CI) in CFB		-0.42 (-0.75, -0.11)		-0.45 (-1.49, 0.48)	
p-value [3]		0.003		0.105	
					0.367

Flushing Severity

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	130	11	9	
Mean (StdDev)	5.57 (2.647)	5.05 (2.549)	6.52 (2.703)	5.34 (2.295)	
Median	5.57	5.19	5.77	5.29	
Min, Max	0.0, 10.0	0.0, 10.0	3.3, 10.0	1.6, 8.9	

Flushing Severity					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	60	128	11	9	
Mean (StdDev)	5.08 (2.590)	4.46 (2.513)	5.65 (3.457)	3.22 (2.567)	
Median	4.89	4.46	4.00	3.23	
Min, Max	0.0, 10.0	0.0, 10.0	1.4, 10.0	0.4, 8.2	
C2D1 CFB					
n	60	126	11	9	
LS Mean (StdErr) [2]	-0.48 (0.190)	-0.64 (0.141)	-0.62 (1.109)	-2.07 (1.406)	
95% CI [2]	-0.86, -0.11	-0.92, -0.36	-2.97, 1.73	-5.05, 0.91	
Difference (95% CI) in CFB [2]		-0.16 (-0.58, 0.26)		-1.45 (-3.65, 0.74)	
p-value [3]		0.464		0.179	

Flushing Severity					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	60	126	11	9	
Mean (StdDev)	4.87 (2.769)	3.99 (2.475)	5.58 (3.447)	3.00 (2.650)	
Median	4.96	3.80	5.14	1.93	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 10.0	0.5, 8.0	
C3D1 CFB					
n	60	124	11	9	
LS Mean (StdErr) [2]	-0.58 (0.235)	-1.04 (0.175)	-0.65 (1.243)	-2.22 (1.576)	
95% CI [2]	-1.05, -0.12	-1.38, -0.69	-3.29, 1.98	-5.56, 1.12	
Difference (95% CI) in CFB [2]		-0.45 (-0.97, 0.07)		-1.57 (-4.03, 0.89)	
p-value [3]		0.087		0.194	

Flushing Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	58	126	10	9	
Mean (StdDev)	4.82 (2.789)	3.78 (2.495)	5.87 (3.423)	2.77 (2.809)	
Median	4.46	3.65	6.11	1.23	
Min, Max	0.0, 10.0	0.0, 10.0	0.2, 10.0	0.0, 8.0	
C4D1 CFB					
n	58	124	10	9	
LS Mean (StdErr) [2]	-0.64 (0.274)	-1.29 (0.200)	-0.75 (1.327)	-2.50 (1.671)	
95% CI [2]	-1.18, -0.10	-1.68, -0.89	-3.58, 2.08	-6.07, 1.06	
Difference (95% CI) in CFB [2]		-0.65 (-1.25, -0.05)		-1.75 (-4.40, 0.90)	
p-value [3]		0.035		0.180	

Flushing Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	58	128	9	9	
Mean (StdDev)	4.63 (2.866)	3.67 (2.496)	7.07 (2.498)	2.43 (2.513)	
Median	4.46	3.59	8.00	1.36	
Min, Max	0.0, 10.0	0.0, 9.8	3.9, 10.0	0.0, 7.2	
C5D1 CFB					
n	58	126	9	9	
LS Mean (StdErr) [2]	-0.89 (0.314)	-1.44 (0.227)	0.01 (1.076)	-3.02 (1.342)	
95% CI [2]	-1.51, -0.27	-1.89, -1.00	-2.29, 2.32	-5.90, -0.14	
Difference (95% CI) in CFB [2]		-0.56 (-1.24, 0.13)		-3.03 (-5.21, -0.85)	
p-value [3]		0.114		0.010	

Flushing Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	56	127	10	9	
Mean (StdDev)	4.57 (2.871)	3.51 (2.528)	6.35 (2.975)	2.32 (2.331)	
Median	4.32	3.36	6.39	1.86	
Min, Max	0.0, 10.0	0.0, 10.0	1.1, 10.0	0.0, 6.6	
C6D1 CFB					
n	56	125	10	9	
LS Mean (StdErr) [2]	-0.94 (0.325)	-1.58 (0.233)	-0.41 (1.079)	-3.05 (1.358)	
95% CI [2]	-1.58, -0.29	-2.04, -1.12	-2.71, 1.88	-5.95, -0.16	
Difference (95% CI) in CFB [2]		-0.64 (-1.36, 0.08)		-2.64 (-4.79, -0.48)	
p-value [3]		0.080		0.020	

Flushing Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	56	124	10	9	
Mean (StdDev)	4.64 (2.808)	3.29 (2.481)	6.44 (2.926)	2.83 (2.639)	
Median	4.49	2.86	6.69	2.07	
Min, Max	0.0, 10.0	0.0, 10.0	1.2, 10.0	0.0, 7.0	
C7D1 CFB					
n	56	122	10	9	
LS Mean (StdErr) [2]	-0.88 (0.340)	-1.66 (0.245)	-0.13 (1.027)	-2.06 (1.293)	
95% CI [2]	-1.55, -0.21	-2.14, -1.18	-2.32, 2.06	-4.82, 0.70	
Difference (95% CI) in CFB [2]		-0.78 (-1.53, -0.03)		-1.93 (-3.98, 0.12)	
Hedges'G (95% CI) in CFB		-0.29 (-0.62, 0.02)		-0.52 (-1.58, 0.40)	
p-value [3]		0.041		0.063	
					0.335

Fatigue Severity

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	130	11	9	
Mean (StdDev)	6.93 (2.015)	6.71 (2.085)	5.53 (1.609)	5.87 (2.578)	
Median	6.86	7.00	5.93	6.86	
Min, Max	0.0, 10.0	0.1, 10.0	2.8, 8.0	0.5, 9.0	

Fatigue Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	60	128	11	9	
Mean (StdDev)	6.42 (2.020)	6.00 (2.293)	5.61 (1.640)	5.47 (2.661)	
Median	6.43	6.14	6.21	6.07	
Min, Max	2.3, 10.0	0.1, 10.0	2.4, 8.3	0.1, 9.0	
C2D1 CFB					
n	60	126	11	9	
LS Mean (StdErr) [2]	-0.53 (0.175)	-0.75 (0.130)	-0.10 (0.323)	-0.65 (0.409)	
95% CI [2]	-0.87, -0.18	-1.01, -0.49	-0.78, 0.58	-1.52, 0.22	
Difference (95% CI) in CFB [2]		-0.22 (-0.61, 0.16)		-0.55 (-1.19, 0.09)	
p-value [3]		0.256		0.085	

Fatigue Severity					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	60	126	11	9	
Mean (StdDev)	5.99 (2.407)	5.59 (2.350)	5.57 (1.913)	5.05 (2.441)	
Median	5.93	5.64	6.00	5.64	
Min, Max	0.3, 10.0	0.2, 10.0	2.2, 8.0	0.7, 8.5	
C3D1 CFB					
n	60	124	11	9	
LS Mean (StdErr) [2]	-0.96 (0.221)	-1.13 (0.164)	-0.04 (0.687)	-0.90 (0.871)	
95% CI [2]	-1.40, -0.52	-1.45, -0.81	-1.49, 1.42	-2.75, 0.94	
Difference (95% CI) in CFB [2]		-0.17 (-0.66, 0.32)		-0.86 (-2.22, 0.49)	
p-value [3]		0.495		0.197	

Fatigue Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	58	126	10	9	
Mean (StdDev)	5.79 (2.474)	5.37 (2.457)	5.09 (2.251)	3.93 (2.662)	
Median	5.82	5.38	6.00	4.50	
Min, Max	0.2, 10.0	0.4, 10.0	1.4, 7.8	0.0, 7.6	
C4D1 CFB					
n	58	124	10	9	
LS Mean (StdErr) [2]	-1.21 (0.255)	-1.40 (0.187)	0.00 (1.393)	-1.38 (1.754)	
95% CI [2]	-1.71, -0.70	-1.77, -1.04	-2.97, 2.97	-5.12, 2.36	
Difference (95% CI) in CFB [2]		-0.20 (-0.76, 0.36)		-1.38 (-4.16, 1.40)	
p-value [3]		0.489		0.307	

Fatigue Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	58	128	9	9	
Mean (StdDev)	5.65 (2.524)	5.36 (2.437)	5.00 (1.789)	3.36 (2.323)	
Median	5.38	5.41	5.71	3.93	
Min, Max	0.6, 10.0	0.1, 10.0	1.5, 7.4	0.0, 6.4	
C5D1 CFB					
n	58	126	9	9	
LS Mean (StdErr) [2]	-1.28 (0.268)	-1.35 (0.193)	-0.01 (1.286)	-1.90 (1.604)	
95% CI [2]	-1.81, -0.75	-1.73, -0.97	-2.77, 2.75	-5.34, 1.54	
Difference (95% CI) in CFB [2]		-0.07 (-0.66, 0.52)		-1.88 (-4.49, 0.72)	
p-value [3]		0.809		0.143	

Fatigue Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	56	127	10	9	
Mean (StdDev)	5.66 (2.532)	5.13 (2.639)	5.33 (1.929)	3.31 (2.244)	
Median	5.63	5.14	5.32	4.38	
Min, Max	0.4, 10.0	0.0, 10.0	2.6, 8.4	0.0, 6.4	
C6D1 CFB					
n	56	125	10	9	
LS Mean (StdErr) [2]	-1.21 (0.293)	-1.53 (0.209)	0.25 (1.324)	-1.78 (1.667)	
95% CI [2]	-1.79, -0.64	-1.94, -1.11	-2.57, 3.07	-5.33, 1.77	
Difference (95% CI) in CFB [2]		-0.31 (-0.96, 0.33)		-2.03 (-4.67, 0.61)	
p-value [3]		0.341		0.122	

Fatigue Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	56	124	10	9	
Mean (StdDev)	5.59 (2.633)	5.01 (2.561)	5.53 (1.817)	3.14 (2.321)	
Median	5.45	5.09	5.82	2.79	
Min, Max	0.2, 10.0	0.0, 10.0	2.8, 7.7	0.0, 6.1	
C7D1 CFB					
n	56	122	10	9	
LS Mean (StdErr) [2]	-1.28 (0.296)	-1.62 (0.214)	0.32 (1.343)	-2.20 (1.690)	
95% CI [2]	-1.86, -0.69	-2.04, -1.19	-2.54, 3.18	-5.81, 1.40	
Difference (95% CI) in CFB [2]		-0.34 (-0.99, 0.32)		-2.52 (-5.20, 0.16)	
Hedges'G (95% CI) in CFB		-0.14 (-0.46, 0.17)		-0.52 (-1.58, 0.40)	
p-value [3]		0.313		0.063	
					0.016

Dizziness Severity					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	130	11	9	
Mean (StdDev)	3.81 (2.849)	3.72 (2.878)	2.27 (1.816)	2.52 (2.634)	
Median	2.93	3.71	2.31	2.23	
Min, Max	0.0, 9.3	0.0, 10.0	0.0, 5.1	0.0, 6.7	

Dizziness Severity					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	60	128	11	9	
Mean (StdDev)	3.31 (2.753)	3.18 (2.652)	2.07 (1.670)	1.87 (2.680)	
Median	2.89	2.96	2.43	0.23	
Min, Max	0.0, 8.7	0.0, 10.0	0.0, 4.8	0.0, 6.1	
C2D1 CFB					
n	60	126	11	9	
LS Mean (StdErr) [2]	-0.42 (0.190)	-0.53 (0.141)	-0.22 (0.587)	-0.92 (0.744)	
95% CI [2]	-0.79, -0.04	-0.81, -0.25	-1.46, 1.03	-2.50, 0.66	
Difference (95% CI) in CFB [2]		-0.12 (-0.54, 0.30)		-0.70 (-1.86, 0.46)	
p-value [3]		0.581		0.218	

Dizziness Severity					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	60	126	11	9	
Mean (StdDev)	2.98 (2.637)	2.85 (2.671)	1.59 (1.755)	1.55 (2.364)	
Median	2.29	2.16	1.57	0.00	
Min, Max	0.0, 8.1	0.0, 10.0	0.0, 4.4	0.0, 6.3	
C3D1 CFB					
n	60	124	11	9	
LS Mean (StdErr) [2]	-0.68 (0.220)	-0.83 (0.164)	-0.53 (0.778)	-1.13 (0.987)	
95% CI [2]	-1.11, -0.25	-1.16, -0.51	-2.18, 1.12	-3.23, 0.96	
Difference (95% CI) in CFB [2]		-0.15 (-0.64, 0.33)		-0.60 (-2.14, 0.94)	
p-value [3]		0.533		0.418	

Dizziness Severity					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	58	126	10	9	
Mean (StdDev)	3.08 (2.716)	2.75 (2.722)	1.88 (1.973)	1.58 (2.327)	
Median	2.50	1.96	1.52	0.57	
Min, Max	0.0, 9.9	0.0, 10.0	0.0, 5.4	0.0, 6.2	
C4D1 CFB					
n	58	124	10	9	
LS Mean (StdErr) [2]	-0.63 (0.266)	-0.98 (0.194)	-0.25 (0.882)	-1.01 (1.110)	
95% CI [2]	-1.15, -0.10	-1.36, -0.59	-2.13, 1.62	-3.37, 1.36	
Difference (95% CI) in CFB [2]		-0.35 (-0.93, 0.23)		-0.75 (-2.51, 1.01)	
p-value [3]		0.239		0.378	

Dizziness Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	58	128	9	9	
Mean (StdDev)	3.05 (2.647)	2.63 (2.637)	2.11 (2.183)	1.29 (2.265)	
Median	2.32	1.93	2.31	0.00	
Min, Max	0.0, 9.6	0.0, 10.0	0.0, 5.3	0.0, 6.6	
C5D1 CFB					
n	58	126	9	9	
LS Mean (StdErr) [2]	-0.59 (0.263)	-1.01 (0.190)	-0.12 (0.725)	-1.41 (0.905)	
95% CI [2]	-1.11, -0.07	-1.38, -0.63	-1.68, 1.43	-3.35, 0.53	
Difference (95% CI) in CFB [2]		-0.42 (-1.00, 0.16)		-1.29 (-2.75, 0.18)	
p-value [3]		0.153		0.081	

Dizziness Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	56	127	10	9	
Mean (StdDev)	2.87 (2.657)	2.38 (2.523)	1.76 (2.063)	1.26 (2.294)	
Median	1.71	1.71	1.11	0.00	
Min, Max	0.0, 8.6	0.0, 10.0	0.0, 4.9	0.0, 6.7	
C6D1 CFB					
n	56	125	10	9	
LS Mean (StdErr) [2]	-0.81 (0.283)	-1.25 (0.202)	-0.35 (0.781)	-1.38 (0.983)	
95% CI [2]	-1.37, -0.25	-1.65, -0.85	-2.02, 1.31	-3.47, 0.72	
Difference (95% CI) in CFB [2]		-0.44 (-1.07, 0.18)		-1.02 (-2.58, 0.54)	
p-value [3]		0.163		0.182	

Dizziness Severity					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	56	124	10	9	
Mean (StdDev)	2.85 (2.700)	2.41 (2.549)	2.02 (2.264)	1.06 (2.205)	
Median	1.93	1.68	1.21	0.14	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 5.6	0.0, 6.8	
C7D1 CFB					
n	56	122	10	9	
LS Mean (StdErr) [2]	-0.86 (0.292)	-1.21 (0.210)	-0.16 (0.934)	-1.57 (1.176)	
95% CI [2]	-1.44, -0.29	-1.62, -0.79	-2.15, 1.83	-4.08, 0.94	
Difference (95% CI) in CFB [2]		-0.35 (-0.99, 0.30)		-1.41 (-3.28, 0.45)	
Hedges'G (95% CI) in CFB		-0.15 (-0.47, 0.17)		-0.42 (-1.46, 0.51)	
p-value [3]		0.291		0.127	
					0.506

Brain Fog Severity					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	130	11	9	
Mean (StdDev)	5.43 (2.719)	5.44 (2.456)	2.84 (1.685)	4.38 (3.106)	
Median	5.76	5.52	3.07	6.00	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 5.1	0.0, 8.0	

Brain Fog Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	60	128	11	9	
Mean (StdDev)	4.88 (2.669)	4.81 (2.654)	2.64 (1.706)	3.68 (3.024)	
Median	4.82	4.67	2.43	3.79	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 5.7	0.0, 8.1	
C2D1 CFB					
n	60	126	11	9	
LS Mean (StdErr) [2]	-0.52 (0.164)	-0.66 (0.122)	0.39 (0.541)	0.09 (0.686)	
95% CI [2]	-0.84, -0.20	-0.90, -0.42	-0.75, 1.54	-1.37, 1.54	
Difference (95% CI) in CFB [2]		-0.14 (-0.50, 0.23)		-0.31 (-1.38, 0.76)	
p-value [3]		0.462		0.551	

Brain Fog Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	60	126	11	9	
Mean (StdDev)	4.64 (2.732)	4.46 (2.706)	2.51 (1.946)	3.62 (2.997)	
Median	4.33	4.33	2.21	4.43	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 6.8	0.0, 7.9	
C3D1 CFB					
n	60	124	11	9	
LS Mean (StdErr) [2]	-0.74 (0.193)	-1.00 (0.144)	-0.07 (0.762)	-0.54 (0.967)	
95% CI [2]	-1.12, -0.36	-1.28, -0.72	-1.68, 1.55	-2.59, 1.51	
Difference (95% CI) in CFB [2]		-0.26 (-0.69, 0.17)		-0.47 (-1.98, 1.03)	
p-value [3]		0.233		0.514	

Brain Fog Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	58	126	10	9	
Mean (StdDev)	4.38 (2.804)	4.26 (2.819)	2.43 (2.136)	3.13 (3.024)	
Median	4.32	3.88	2.25	3.71	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 6.9	0.0, 7.1	
C4D1 CFB					
n	58	124	10	9	
LS Mean (StdErr) [2]	-0.97 (0.239)	-1.20 (0.175)	0.11 (0.973)	-0.61 (1.225)	
95% CI [2]	-1.44, -0.50	-1.55, -0.86	-1.97, 2.18	-3.23, 2.00	
Difference (95% CI) in CFB [2]		-0.23 (-0.76, 0.29)		-0.72 (-2.66, 1.22)	
p-value [3]		0.388		0.441	

Brain Fog Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	58	128	9	9	
Mean (StdDev)	4.18 (2.852)	4.26 (2.835)	2.17 (1.484)	2.87 (2.931)	
Median	3.80	4.48	2.15	2.21	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 4.3	0.0, 6.6	
C5D1 CFB					
n	58	126	9	9	
LS Mean (StdErr) [2]	-1.08 (0.262)	-1.11 (0.190)	0.09 (0.866)	-0.90 (1.080)	
95% CI [2]	-1.59, -0.56	-1.48, -0.73	-1.77, 1.95	-3.21, 1.42	
Difference (95% CI) in CFB [2]		-0.03 (-0.61, 0.55)		-0.98 (-2.74, 0.77)	
p-value [3]		0.919		0.248	

Brain Fog Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	56	127	10	9	
Mean (StdDev)	4.18 (2.794)	4.06 (2.864)	2.78 (2.329)	3.06 (3.184)	
Median	3.89	3.77	2.54	1.86	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 7.9	0.0, 7.7	
C6D1 CFB					
n	56	125	10	9	
LS Mean (StdErr) [2]	-0.99 (0.257)	-1.28 (0.184)	0.31 (0.979)	-0.91 (1.233)	
95% CI [2]	-1.50, -0.48	-1.65, -0.92	-1.77, 2.40	-3.53, 1.72	
Difference (95% CI) in CFB [2]		-0.30 (-0.86, 0.27)		-1.22 (-3.17, 0.74)	
p-value [3]		0.305		0.204	

Brain Fog Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	56	124	10	9	
Mean (StdDev)	4.17 (2.906)	4.01 (2.911)	3.03 (2.471)	2.86 (3.045)	
Median	3.75	3.76	2.57	1.36	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 7.9	0.0, 7.1	
C7D1 CFB					
n	56	122	10	9	
LS Mean (StdErr) [2]	-1.04 (0.272)	-1.32 (0.196)	0.42 (0.892)	-1.34 (1.123)	
95% CI [2]	-1.57, -0.50	-1.71, -0.94	-1.48, 2.32	-3.73, 1.06	
Difference (95% CI) in CFB [2]		-0.29 (-0.89, 0.31)		-1.76 (-3.54, 0.03)	
Hedges'G (95% CI) in CFB		-0.13 (-0.45, 0.18)		-0.54 (-1.61, 0.37)	
p-value [3]		0.347		0.053	
					0.185

Headache Severity					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	130	11	9	
Mean (StdDev)	4.46 (2.681)	4.06 (2.574)	2.14 (2.004)	3.38 (2.316)	
Median	4.79	3.87	2.14	3.36	
Min, Max	0.3, 9.9	0.0, 9.9	0.0, 6.1	0.0, 7.4	

Headache Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	60	128	11	9	
Mean (StdDev)	4.10 (2.601)	3.50 (2.447)	1.99 (1.737)	3.03 (2.331)	
Median	4.05	3.21	1.79	3.36	
Min, Max	0.0, 9.1	0.0, 10.0	0.0, 5.5	0.0, 6.5	
C2D1 CFB					
n	60	126	11	9	
LS Mean (StdErr) [2]	-0.31 (0.170)	-0.57 (0.127)	-0.13 (0.758)	-0.51 (0.962)	
95% CI [2]	-0.65, 0.02	-0.82, -0.32	-1.74, 1.47	-2.55, 1.53	
Difference (95% CI) in CFB [2]		-0.26 (-0.63, 0.12)		-0.37 (-1.87, 1.13)	
p-value [3]		0.180		0.606	

Headache Severity					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	60	126	11	9	
Mean (StdDev)	3.68 (2.557)	3.18 (2.388)	1.93 (2.170)	2.65 (2.663)	
Median	3.21	2.63	1.43	2.79	
Min, Max	0.0, 9.1	0.0, 10.0	0.0, 6.6	0.0, 6.8	
C3D1 CFB					
n	60	124	11	9	
LS Mean (StdErr) [2]	-0.67 (0.220)	-0.84 (0.164)	-0.59 (0.901)	-1.54 (1.142)	
95% CI [2]	-1.11, -0.24	-1.16, -0.52	-2.50, 1.32	-3.96, 0.88	
Difference (95% CI) in CFB [2]		-0.17 (-0.66, 0.32)		-0.95 (-2.73, 0.83)	
p-value [3]		0.498		0.276	

Headache Severity					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	58	126	10	9	
Mean (StdDev)	3.71 (2.484)	3.02 (2.374)	2.09 (2.134)	2.63 (2.547)	
Median	3.43	2.69	1.61	3.08	
Min, Max	0.0, 8.4	0.0, 9.9	0.0, 6.4	0.1, 6.7	
C4D1 CFB					
n	58	124	10	9	
LS Mean (StdErr) [2]	-0.72 (0.247)	-1.06 (0.181)	-0.48 (0.873)	-1.54 (1.099)	
95% CI [2]	-1.21, -0.23	-1.41, -0.70	-2.34, 1.38	-3.88, 0.80	
Difference (95% CI) in CFB [2]		-0.34 (-0.88, 0.21)		-1.06 (-2.81, 0.68)	
p-value [3]		0.225		0.214	

Headache Severity					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	58	128	9	9	
Mean (StdDev)	3.60 (2.498)	2.98 (2.359)	2.21 (2.104)	1.72 (2.331)	
Median	3.39	2.54	2.07	0.50	
Min, Max	0.0, 9.1	0.0, 10.0	0.0, 6.6	0.0, 7.0	
C5D1 CFB					
n	58	126	9	9	
LS Mean (StdErr) [2]	-0.87 (0.248)	-1.15 (0.179)	-0.43 (0.853)	-2.16 (1.064)	
95% CI [2]	-1.36, -0.38	-1.51, -0.80	-2.26, 1.40	-4.44, 0.12	
Difference (95% CI) in CFB [2]		-0.29 (-0.83, 0.26)		-1.73 (-3.45, -0.00)	
p-value [3]		0.303		0.050	

Headache Severity					
	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	56	127	10	9	
Mean (StdDev)	3.35 (2.501)	2.76 (2.406)	1.90 (2.074)	1.59 (2.239)	
Median	2.88	2.08	1.25	1.07	
Min, Max	0.0, 8.9	0.0, 10.0	0.0, 6.2	0.0, 7.0	
C6D1 CFB					
n	56	125	10	9	
LS Mean (StdErr) [2]	-1.03 (0.262)	-1.33 (0.187)	-0.42 (0.651)	-2.15 (0.820)	
95% CI [2]	-1.55, -0.52	-1.70, -0.96	-1.81, 0.97	-3.89, -0.40	
Difference (95% CI) in CFB [2]		-0.30 (-0.88, 0.28)		-1.73 (-3.03, -0.43)	
p-value [3]		0.305		0.013	

Headache Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	56	124	10	9	
Mean (StdDev)	3.42 (2.597)	2.73 (2.365)	2.09 (2.300)	1.63 (2.232)	
Median	2.89	2.11	1.61	0.79	
Min, Max	0.0, 8.9	0.0, 10.0	0.0, 6.7	0.0, 6.7	
C7D1 CFB					
n	56	122	10	9	
LS Mean (StdErr) [2]	-0.95 (0.262)	-1.30 (0.189)	-0.81 (0.715)	-2.98 (0.900)	
95% CI [2]	-1.46, -0.43	-1.67, -0.93	-2.34, 0.71	-4.90, -1.06	
Difference (95% CI) in CFB [2]		-0.36 (-0.93, 0.22)		-2.17 (-3.60, -0.74)	
Hedges'G (95% CI) in CFB		-0.17 (-0.49, 0.14)		-0.84 (-1.97, 0.07)	
p-value [3]		0.226		0.006	
					0.170

Diarrhea Count	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	130	11	9	
Mean (StdDev)	1.65 (1.533)	1.45 (1.687)	0.63 (0.627)	1.27 (0.914)	
Median	1.32	0.96	0.43	1.07	
Min, Max	0.0, 7.2	0.0, 12.2	0.0, 1.8	0.0, 2.7	

Diarrhea Count	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	60	128	11	9	
Mean (StdDev)	1.35 (1.312)	1.10 (1.448)	0.58 (0.825)	1.04 (0.804)	
Median	0.93	0.65	0.36	0.93	
Min, Max	0.0, 4.9	0.0, 10.7	0.0, 2.8	0.0, 2.4	
C2D1 CFB					
n	60	126	11	9	
LS Mean (StdErr) [2]	-0.36 (0.120)	-0.43 (0.089)	-0.24 (0.268)	-0.42 (0.340)	
95% CI [2]	-0.59, -0.12	-0.61, -0.26	-0.81, 0.33	-1.14, 0.30	
Difference (95% CI) in CFB [2]		-0.08 (-0.34, 0.19)		-0.18 (-0.71, 0.35)	
p-value [3]		0.563		0.480	

Diarrhea Count	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	60	126	11	9	
Mean (StdDev)	1.23 (1.209)	1.00 (1.203)	0.58 (0.685)	0.77 (0.857)	
Median	0.93	0.65	0.36	0.43	
Min, Max	0.0, 4.4	0.0, 5.8	0.0, 2.2	0.0, 2.7	
C3D1 CFB					
n	60	124	11	9	
LS Mean (StdErr) [2]	-0.50 (0.158)	-0.57 (0.117)	-0.06 (0.289)	-0.43 (0.367)	
95% CI [2]	-0.81, -0.18	-0.80, -0.33	-0.67, 0.56	-1.21, 0.35	
Difference (95% CI) in CFB [2]		-0.07 (-0.42, 0.28)		-0.37 (-0.94, 0.20)	
p-value [3]		0.694		0.186	

Diarrhea Count	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	58	126	10	9	
Mean (StdDev)	1.22 (1.165)	1.01 (1.392)	0.52 (0.719)	0.76 (0.924)	
Median	0.78	0.52	0.36	0.36	
Min, Max	0.0, 4.8	0.0, 9.0	0.0, 2.3	0.0, 2.8	
C4D1 CFB					
n	58	124	10	9	
LS Mean (StdErr) [2]	-0.52 (0.152)	-0.54 (0.111)	-0.24 (0.334)	-0.50 (0.421)	
95% CI [2]	-0.82, -0.22	-0.76, -0.32	-0.95, 0.48	-1.40, 0.40	
Difference (95% CI) in CFB [2]		-0.02 (-0.36, 0.31)		-0.26 (-0.93, 0.40)	
p-value [3]		0.896		0.413	

Diarrhea Count	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	58	128	9	9	
Mean (StdDev)	1.22 (1.198)	1.01 (1.458)	0.61 (1.027)	0.74 (1.098)	
Median	0.78	0.50	0.21	0.43	
Min, Max	0.0, 4.8	0.0, 9.6	0.0, 3.1	0.0, 3.4	
C5D1 CFB					
n	58	126	9	9	
LS Mean (StdErr) [2]	-0.53 (0.169)	-0.57 (0.122)	-0.15 (0.535)	-0.68 (0.667)	
95% CI [2]	-0.87, -0.20	-0.81, -0.32	-1.30, 1.00	-2.11, 0.75	
Difference (95% CI) in CFB [2]		-0.03 (-0.40, 0.34)		-0.53 (-1.61, 0.55)	
p-value [3]		0.870		0.310	

Diarrhea Count	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	56	127	10	9	
Mean (StdDev)	1.18 (1.328)	0.93 (1.290)	0.34 (0.403)	0.76 (1.213)	
Median	0.68	0.46	0.18	0.36	
Min, Max	0.0, 6.5	0.0, 9.0	0.0, 1.2	0.0, 3.9	
C6D1 CFB					
n	56	125	10	9	
LS Mean (StdErr) [2]	-0.49 (0.147)	-0.59 (0.105)	-0.32 (0.462)	-0.46 (0.581)	
95% CI [2]	-0.78, -0.20	-0.80, -0.38	-1.31, 0.66	-1.70, 0.78	
Difference (95% CI) in CFB [2]		-0.10 (-0.43, 0.22)		-0.14 (-1.06, 0.79)	
p-value [3]		0.534		0.757	

Diarrhea Count	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	56	124	10	9	
Mean (StdDev)	1.15 (1.298)	0.83 (1.089)	0.46 (0.537)	0.81 (1.337)	
Median	0.82	0.28	0.32	0.33	
Min, Max	0.0, 5.9	0.0, 4.8	0.0, 1.9	0.0, 4.2	
C7D1 CFB					
n	56	122	10	9	
LS Mean (StdErr) [2]	-0.48 (0.161)	-0.59 (0.116)	-0.26 (0.464)	-0.50 (0.584)	
95% CI [2]	-0.80, -0.16	-0.82, -0.36	-1.25, 0.73	-1.74, 0.75	
Difference (95% CI) in CFB [2]		-0.11 (-0.46, 0.24)		-0.24 (-1.16, 0.69)	
Hedges'G (95% CI) in CFB		-0.09 (-0.41, 0.23)		-0.14 (-1.13, 0.81)	
p-value [3]		0.540		0.596	
					0.881

Diarrhea Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	130	11	9	
Mean (StdDev)	3.41 (2.645)	2.91 (2.419)	1.18 (1.306)	2.67 (2.149)	
Median	2.93	2.45	1.15	2.33	
Min, Max	0.0, 9.5	0.0, 9.5	0.0, 4.4	0.0, 6.2	

Diarrhea Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	60	128	11	9	
Mean (StdDev)	2.66 (2.473)	2.30 (2.371)	0.82 (0.831)	2.31 (1.878)	
Median	2.21	1.39	0.50	2.00	
Min, Max	0.0, 9.1	0.0, 8.9	0.0, 2.3	0.0, 5.0	
C2D1 CFB					
n	60	126	11	9	
LS Mean (StdErr) [2]	-0.63 (0.199)	-0.54 (0.148)	-1.32 (0.305)	-1.45 (0.386)	
95% CI [2]	-1.02, -0.24	-0.83, -0.25	-1.97, -0.68	-2.27, -0.63	
Difference (95% CI) in CFB [2]		0.09 (-0.35, 0.53)		-0.13 (-0.73, 0.47)	
p-value [3]		0.696		0.657	

Diarrhea Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	60	126	11	9	
Mean (StdDev)	2.47 (2.368)	2.12 (2.271)	1.02 (1.151)	1.62 (1.739)	
Median	1.50	1.18	0.50	0.79	
Min, Max	0.0, 8.7	0.0, 9.5	0.0, 2.9	0.0, 5.0	
C3D1 CFB					
n	60	124	11	9	
LS Mean (StdErr) [2]	-0.83 (0.242)	-0.73 (0.180)	-0.64 (0.617)	-1.43 (0.782)	
95% CI [2]	-1.30, -0.35	-1.09, -0.38	-1.95, 0.66	-3.09, 0.23	
Difference (95% CI) in CFB [2]		0.10 (-0.44, 0.63)		-0.79 (-2.01, 0.43)	
p-value [3]		0.725		0.189	

Diarrhea Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	58	126	10	9	
Mean (StdDev)	2.67 (2.408)	2.05 (2.301)	0.90 (1.139)	1.60 (1.727)	
Median	2.11	1.16	0.45	0.86	
Min, Max	0.0, 8.3	0.0, 8.9	0.0, 2.9	0.0, 5.0	
C4D1 CFB					
n	58	124	10	9	
LS Mean (StdErr) [2]	-0.71 (0.240)	-0.83 (0.176)	-0.89 (0.573)	-1.51 (0.721)	
95% CI [2]	-1.18, -0.23	-1.17, -0.48	-2.11, 0.33	-3.05, 0.02	
Difference (95% CI) in CFB [2]		-0.12 (-0.65, 0.41)		-0.62 (-1.77, 0.52)	
p-value [3]		0.655		0.265	

Diarrhea Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	58	128	9	9	
Mean (StdDev)	2.61 (2.416)	2.00 (2.227)	1.00 (1.273)	1.33 (1.797)	
Median	1.89	1.18	0.38	0.86	
Min, Max	0.0, 8.5	0.0, 9.0	0.0, 3.1	0.0, 5.0	
C5D1 CFB					
n	58	126	9	9	
LS Mean (StdErr) [2]	-0.77 (0.266)	-0.90 (0.192)	-1.15 (0.747)	-2.25 (0.932)	
95% CI [2]	-1.29, -0.24	-1.28, -0.53	-2.75, 0.45	-4.25, -0.25	
Difference (95% CI) in CFB [2]		-0.14 (-0.72, 0.44)		-1.10 (-2.61, 0.41)	
p-value [3]		0.638		0.141	

Diarrhea Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	56	127	10	9	
Mean (StdDev)	2.44 (2.418)	1.85 (2.195)	0.75 (1.009)	1.34 (1.735)	
Median	1.63	1.14	0.23	0.71	
Min, Max	0.0, 8.6	0.0, 8.9	0.0, 2.8	0.0, 5.0	
C6D1 CFB					
n	56	125	10	9	
LS Mean (StdErr) [2]	-0.76 (0.255)	-0.95 (0.182)	-0.76 (0.654)	-1.44 (0.823)	
95% CI [2]	-1.27, -0.26	-1.31, -0.59	-2.15, 0.64	-3.19, 0.32	
Difference (95% CI) in CFB [2]		-0.19 (-0.75, 0.37)		-0.68 (-1.99, 0.63)	
p-value [3]		0.501		0.284	

Diarrhea Severity	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	56	124	10	9	
Mean (StdDev)	2.41 (2.532)	1.81 (2.219)	0.94 (1.168)	1.32 (1.706)	
Median	1.37	0.71	0.48	0.71	
Min, Max	0.0, 8.6	0.0, 8.7	0.0, 3.2	0.0, 5.0	
C7D1 CFB					
n	56	122	10	9	
LS Mean (StdErr) [2]	-0.81 (0.277)	-0.96 (0.200)	-0.73 (0.621)	-1.74 (0.782)	
95% CI [2]	-1.35, -0.26	-1.35, -0.56	-2.05, 0.59	-3.41, -0.08	
Difference (95% CI) in CFB [2]		-0.15 (-0.76, 0.46)		-1.01 (-2.25, 0.23)	
Hedges'G (95% CI) in CFB		-0.07 (-0.39, 0.25)		-0.45 (-1.50, 0.47)	
p-value [3]		0.623		0.102	
					0.422

Bone Pain Severity					
	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	17	41	54	98	
Mean (StdDev)	5.10 (2.554)	4.53 (2.606)	5.50 (2.422)	5.58 (2.537)	
Median	4.79	4.14	5.79	6.11	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 9.4	0.0, 10.0	

Bone Pain Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	17	40	54	97	
Mean (StdDev)	4.17 (2.478)	4.09 (2.731)	5.01 (2.584)	4.73 (2.682)	
Median	4.21	3.79	5.52	5.07	
Min, Max	0.0, 10.0	0.0, 9.3	0.0, 9.0	0.0, 10.0	
C2D1 CFB					
n	17	40	54	95	
LS Mean (StdErr) [2]	-1.06 (0.232)	-0.54 (0.160)	-0.32 (0.199)	-0.72 (0.167)	
95% CI [2]	-1.53, -0.60	-0.86, -0.22	-0.71, 0.07	-1.05, -0.39	
Difference (95% CI) in CFB [2]		0.52 (-0.00, 1.05)		-0.40 (-0.84, 0.04)	
p-value [3]		0.051		0.072	

Bone Pain Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	40	54	95	
Mean (StdDev)	4.08 (2.840)	3.99 (2.582)	4.85 (2.621)	4.43 (2.819)	
Median	3.82	3.26	5.39	4.29	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 9.1	0.0, 10.0	
C3D1 CFB					
n	17	40	54	93	
LS Mean (StdErr) [2]	-1.13 (0.301)	-0.63 (0.207)	-0.55 (0.236)	-1.08 (0.198)	
95% CI [2]	-1.74, -0.53	-1.05, -0.22	-1.02, -0.08	-1.47, -0.69	
Difference (95% CI) in CFB [2]		0.50 (-0.18, 1.18)		-0.53 (-1.05, -0.01)	
p-value [3]		0.149		0.046	

Bone Pain Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	17	40	51	95	
Mean (StdDev)	3.99 (2.961)	3.91 (2.692)	4.93 (2.651)	4.44 (2.878)	
Median	3.36	3.37	5.14	4.21	
Min, Max	0.0, 9.8	0.0, 9.8	0.0, 9.4	0.0, 10.0	
C4D1 CFB					
n	17	40	51	93	
LS Mean (StdErr) [2]	-1.16 (0.359)	-0.66 (0.247)	-0.45 (0.286)	-0.97 (0.233)	
95% CI [2]	-1.88, -0.44	-1.15, -0.16	-1.02, 0.11	-1.43, -0.50	
Difference (95% CI) in CFB [2]		0.50 (-0.31, 1.32)		-0.51 (-1.13, 0.11)	
p-value [3]		0.223		0.104	

Bone Pain Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	40	50	97	
Mean (StdDev)	4.04 (2.935)	3.77 (2.419)	4.92 (2.649)	4.17 (2.985)	
Median	3.21	3.52	5.25	4.10	
Min, Max	0.0, 9.8	0.0, 8.9	0.0, 9.3	0.0, 10.0	
C5D1 CFB					
n	17	40	50	95	
LS Mean (StdErr) [2]	-0.93 (0.384)	-0.64 (0.264)	-0.47 (0.307)	-1.20 (0.243)	
95% CI [2]	-1.70, -0.16	-1.17, -0.11	-1.08, 0.14	-1.69, -0.72	
Difference (95% CI) in CFB [2]		0.29 (-0.58, 1.17)		-0.73 (-1.40, -0.07)	
p-value [3]		0.500		0.031	

Bone Pain Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	17	40	49	96	
Mean (StdDev)	4.25 (2.984)	3.70 (2.251)	4.80 (2.634)	4.01 (2.936)	
Median	3.50	3.46	5.00	3.75	
Min, Max	0.0, 9.1	0.0, 9.1	0.0, 9.6	0.0, 10.0	
C6D1 CFB					
n	17	40	49	94	
LS Mean (StdErr) [2]	-0.68 (0.439)	-0.73 (0.303)	-0.44 (0.309)	-1.30 (0.245)	
95% CI [2]	-1.56, 0.20	-1.34, -0.13	-1.05, 0.17	-1.79, -0.82	
Difference (95% CI) in CFB [2]		-0.05 (-1.05, 0.94)		-0.87 (-1.54, -0.19)	
p-value [3]		0.915		0.012	

Bone Pain Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	17	40	49	93	
Mean (StdDev)	3.98 (2.678)	3.69 (2.273)	4.83 (2.697)	3.93 (2.976)	
Median	3.29	3.26	5.36	3.62	
Min, Max	0.0, 9.0	0.0, 9.0	0.0, 9.4	0.0, 10.0	
C7D1 CFB					
n	17	40	49	91	
LS Mean (StdErr) [2]	-1.01 (0.419)	-0.74 (0.288)	-0.47 (0.324)	-1.36 (0.259)	
95% CI [2]	-1.85, -0.17	-1.32, -0.16	-1.11, 0.17	-1.87, -0.85	
Difference (95% CI) in CFB [2]		0.27 (-0.68, 1.23)		-0.89 (-1.60, -0.18)	
Hedges'G (95% CI) in CFB		0.15 (-0.42, 0.74)		-0.37 (-0.73, -0.02)	
p-value [3]		0.566		0.014	
					0.074

Abdominal Pain Severity					
	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	17	41	54	98	
Mean (StdDev)	4.51 (2.810)	3.39 (2.160)	3.82 (2.366)	4.08 (2.297)	
Median	4.93	3.00	3.78	4.00	
Min, Max	0.0, 8.7	0.0, 9.8	0.0, 9.6	0.0, 9.6	

Abdominal Pain Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	17	40	54	97	
Mean (StdDev)	3.44 (2.001)	2.64 (1.967)	3.17 (2.285)	3.37 (2.226)	
Median	3.64	2.51	3.04	3.10	
Min, Max	0.0, 7.0	0.0, 7.1	0.0, 8.9	0.0, 9.4	
C2D1 CFB					
n	17	40	54	95	
LS Mean (StdErr) [2]	-1.04 (0.327)	-0.68 (0.225)	-0.56 (0.162)	-0.67 (0.135)	
95% CI [2]	-1.69, -0.38	-1.13, -0.23	-0.88, -0.24	-0.93, -0.40	
Difference (95% CI) in CFB [2]		0.36 (-0.38, 1.10)		-0.11 (-0.46, 0.25)	
p-value [3]		0.335		0.557	

Abdominal Pain Severity

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	40	54	95	
Mean (StdDev)	2.92 (2.192)	2.50 (1.895)	3.10 (2.266)	2.89 (2.282)	
Median	3.00	2.34	2.78	2.43	
Min, Max	0.0, 7.6	0.0, 7.6	0.0, 8.4	0.0, 8.3	
C3D1 CFB					
n	17	40	54	93	
LS Mean (StdErr) [2]	-1.54 (0.371)	-0.82 (0.255)	-0.60 (0.212)	-1.10 (0.178)	
95% CI [2]	-2.29, -0.80	-1.33, -0.30	-1.02, -0.18	-1.45, -0.74	
Difference (95% CI) in CFB [2]		0.73 (-0.12, 1.57)		-0.49 (-0.96, -0.03)	
p-value [3]		0.089		0.039	

Abdominal Pain Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	17	40	51	95	
Mean (StdDev)	2.78 (2.288)	2.22 (1.936)	3.09 (2.178)	2.65 (2.273)	
Median	3.00	1.95	3.07	2.36	
Min, Max	0.0, 7.4	0.0, 7.1	0.0, 7.9	0.0, 9.1	
C4D1 CFB					
n	17	40	51	93	
LS Mean (StdErr) [2]	-1.63 (0.444)	-1.05 (0.306)	-0.69 (0.255)	-1.37 (0.208)	
95% CI [2]	-2.52, -0.74	-1.66, -0.44	-1.19, -0.18	-1.78, -0.96	
Difference (95% CI) in CFB [2]		0.58 (-0.43, 1.59)		-0.68 (-1.23, -0.12)	
p-value [3]		0.253		0.017	

Abdominal Pain Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	40	50	97	
Mean (StdDev)	2.74 (2.181)	2.09 (1.777)	3.23 (2.229)	2.56 (2.430)	
Median	2.50	1.93	3.00	1.85	
Min, Max	0.0, 6.9	0.0, 6.9	0.0, 8.1	0.0, 9.4	
C5D1 CFB					
n	17	40	50	95	
LS Mean (StdErr) [2]	-1.60 (0.418)	-1.11 (0.288)	-0.57 (0.295)	-1.46 (0.234)	
95% CI [2]	-2.44, -0.76	-1.68, -0.53	-1.15, 0.02	-1.92, -0.99	
Difference (95% CI) in CFB [2]		0.49 (-0.46, 1.44)		-0.89 (-1.53, -0.25)	
p-value [3]		0.305		0.007	

Abdominal Pain Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	17	40	49	96	
Mean (StdDev)	2.42 (2.047)	2.03 (1.802)	2.66 (2.114)	2.38 (2.375)	
Median	2.54	1.90	2.29	1.74	
Min, Max	0.0, 6.9	0.0, 7.3	0.0, 7.1	0.0, 9.6	
C6D1 CFB					
n	17	40	49	94	
LS Mean (StdErr) [2]	-1.95 (0.475)	-1.26 (0.327)	-0.89 (0.289)	-1.53 (0.229)	
95% CI [2]	-2.90, -1.00	-1.92, -0.61	-1.46, -0.32	-1.99, -1.08	
Difference (95% CI) in CFB [2]		0.69 (-0.39, 1.76)		-0.64 (-1.28, -0.01)	
p-value [3]		0.208		0.046	

Abdominal Pain Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	17	40	49	93	
Mean (StdDev)	2.60 (2.230)	2.09 (1.831)	2.83 (2.334)	2.41 (2.324)	
Median	2.29	2.00	2.43	1.82	
Min, Max	0.0, 7.6	0.0, 7.2	0.0, 8.3	0.0, 9.4	
C7D1 CFB					
n	17	40	49	91	
LS Mean (StdErr) [2]	-1.77 (0.470)	-1.15 (0.324)	-0.83 (0.283)	-1.57 (0.226)	
95% CI [2]	-2.71, -0.83	-1.79, -0.50	-1.39, -0.27	-2.02, -1.13	
Difference (95% CI) in CFB [2]		0.63 (-0.44, 1.69)		-0.74 (-1.36, -0.13)	
Hedges'G (95% CI) in CFB		0.31 (-0.26, 0.90)		-0.35 (-0.71, -0.01)	
p-value [3]		0.245		0.019	
					0.023

Nausea Severity					
	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	17	41	54	98	
Mean (StdDev)	3.50 (2.738)	2.72 (2.240)	3.32 (2.449)	3.03 (2.670)	
Median	3.71	2.38	2.78	2.50	
Min, Max	0.0, 7.6	0.0, 8.5	0.0, 8.9	0.0, 9.0	

Nausea Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	17	40	54	97	
Mean (StdDev)	3.30 (2.104)	2.42 (2.090)	2.72 (2.446)	2.61 (2.429)	
Median	3.71	2.00	2.18	2.25	
Min, Max	0.0, 6.6	0.0, 7.1	0.0, 8.3	0.0, 8.8	
C2D1 CFB					
n	17	40	54	95	
LS Mean (StdErr) [2]	-0.24 (0.333)	-0.30 (0.229)	-0.46 (0.182)	-0.33 (0.152)	
95% CI [2]	-0.91, 0.43	-0.76, 0.15	-0.82, -0.10	-0.63, -0.03	
Difference (95% CI) in CFB [2]		-0.06 (-0.82, 0.69)		0.14 (-0.26, 0.54)	
p-value [3]		0.869		0.504	

Nausea Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	40	54	95	
Mean (StdDev)	2.62 (2.290)	2.43 (1.853)	2.50 (2.324)	2.24 (2.398)	
Median	2.36	2.14	1.89	1.23	
Min, Max	0.0, 7.6	0.0, 7.4	0.0, 7.7	0.0, 8.9	
C3D1 CFB					
n	17	40	54	93	
LS Mean (StdErr) [2]	-0.86 (0.346)	-0.24 (0.238)	-0.80 (0.228)	-0.81 (0.191)	
95% CI [2]	-1.55, -0.16	-0.72, 0.23	-1.25, -0.34	-1.19, -0.43	
Difference (95% CI) in CFB [2]		0.62 (-0.17, 1.40)		-0.02 (-0.52, 0.49)	
p-value [3]		0.122		0.952	

Nausea Severity

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	17	40	51	95	
Mean (StdDev)	2.51 (2.293)	2.05 (1.971)	2.62 (2.248)	1.99 (2.317)	
Median	2.07	1.68	2.00	1.14	
Min, Max	0.0, 7.4	0.0, 8.0	0.0, 7.3	0.0, 9.2	
C4D1 CFB					
n	17	40	51	93	
LS Mean (StdErr) [2]	-1.04 (0.395)	-0.67 (0.272)	-0.78 (0.261)	-1.09 (0.213)	
95% CI [2]	-1.83, -0.24	-1.22, -0.13	-1.29, -0.26	-1.51, -0.66	
Difference (95% CI) in CFB [2]		0.36 (-0.54, 1.26)		-0.31 (-0.88, 0.26)	
p-value [3]		0.423		0.284	

Nausea Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	40	50	97	
Mean (StdDev)	2.61 (2.158)	1.85 (1.666)	2.65 (2.274)	2.05 (2.407)	
Median	3.07	1.68	2.48	1.21	
Min, Max	0.0, 6.9	0.0, 7.1	0.0, 8.5	0.0, 8.9	
C5D1 CFB					
n	17	40	50	95	
LS Mean (StdErr) [2]	-0.88 (0.364)	-0.84 (0.250)	-0.78 (0.299)	-1.01 (0.236)	
95% CI [2]	-1.61, -0.15	-1.35, -0.34	-1.37, -0.19	-1.47, -0.54	
Difference (95% CI) in CFB [2]		0.04 (-0.79, 0.87)		-0.23 (-0.88, 0.42)	
p-value [3]		0.925		0.486	

Nausea Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	17	40	49	96	
Mean (StdDev)	2.34 (2.206)	1.70 (1.674)	2.30 (2.114)	1.82 (2.309)	
Median	1.86	1.46	2.00	0.82	
Min, Max	0.0, 7.3	0.0, 6.9	0.0, 7.9	0.0, 9.9	
C6D1 CFB					
n	17	40	49	94	
LS Mean (StdErr) [2]	-1.21 (0.408)	-1.09 (0.281)	-1.04 (0.288)	-1.17 (0.229)	
95% CI [2]	-2.03, -0.39	-1.65, -0.52	-1.61, -0.47	-1.62, -0.71	
Difference (95% CI) in CFB [2]		0.12 (-0.80, 1.05)		-0.13 (-0.76, 0.50)	
p-value [3]		0.792		0.690	

Nausea Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	17	40	49	93	
Mean (StdDev)	2.36 (2.389)	1.79 (1.677)	2.43 (2.263)	1.85 (2.310)	
Median	1.08	1.63	1.79	0.92	
Min, Max	0.0, 7.7	0.0, 7.2	0.0, 7.3	0.0, 9.5	
C7D1 CFB					
n	17	40	49	91	
LS Mean (StdErr) [2]	-1.16 (0.420)	-0.93 (0.289)	-0.92 (0.316)	-1.14 (0.253)	
95% CI [2]	-2.01, -0.32	-1.51, -0.35	-1.54, -0.29	-1.64, -0.64	
Difference (95% CI) in CFB [2]		0.23 (-0.72, 1.19)		-0.23 (-0.92, 0.46)	
Hedges'G (95% CI) in CFB		0.13 (-0.45, 0.71)		-0.10 (-0.45, 0.25)	
p-value [3]		0.628		0.519	
					0.466

Spots Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	17	41	54	98	
Mean (StdDev)	6.07 (3.077)	4.49 (2.971)	5.68 (3.177)	5.63 (3.014)	
Median	7.00	4.29	6.32	6.14	
Min, Max	1.0, 10.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	

Spots Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	17	40	54	97	
Mean (StdDev)	5.39 (2.870)	3.99 (2.694)	5.39 (3.003)	4.63 (2.817)	
Median	5.57	4.00	5.71	4.93	
Min, Max	1.0, 10.0	0.0, 9.1	0.0, 10.0	0.0, 10.0	
C2D1 CFB					
n	17	40	54	95	
LS Mean (StdErr) [2]	-0.66 (0.310)	-0.51 (0.213)	-0.19 (0.188)	-0.95 (0.157)	
95% CI [2]	-1.28, -0.04	-0.94, -0.08	-0.57, 0.18	-1.26, -0.64	
Difference (95% CI) in CFB [2]		0.15 (-0.56, 0.85)		-0.75 (-1.17, -0.34)	
p-value [3]		0.678		<0.001	

Spots Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	40	54	95	
Mean (StdDev)	5.54 (3.168)	3.64 (2.584)	5.29 (2.954)	4.21 (2.660)	
Median	5.43	3.15	5.41	4.07	
Min, Max	0.0, 10.0	0.0, 9.8	0.0, 10.0	0.0, 9.3	
C3D1 CFB					
n	17	40	54	93	
LS Mean (StdErr) [2]	-0.41 (0.367)	-0.76 (0.252)	-0.18 (0.232)	-1.28 (0.194)	
95% CI [2]	-1.14, 0.33	-1.27, -0.26	-0.64, 0.28	-1.67, -0.90	
Difference (95% CI) in CFB [2]		-0.36 (-1.19, 0.48)		-1.10 (-1.61, -0.59)	
p-value [3]		0.394		<0.0001	

Spots Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	17	40	51	95	
Mean (StdDev)	5.51 (3.150)	3.42 (2.600)	5.16 (2.990)	4.01 (2.638)	
Median	5.64	3.04	5.31	3.85	
Min, Max	1.0, 10.0	0.0, 9.3	0.0, 10.0	0.0, 9.4	
C4D1 CFB					
n	17	40	51	93	
LS Mean (StdErr) [2]	-0.29 (0.393)	-0.84 (0.271)	-0.16 (0.245)	-1.42 (0.200)	
95% CI [2]	-1.08, 0.50	-1.38, -0.30	-0.65, 0.33	-1.82, -1.03	
Difference (95% CI) in CFB [2]		-0.55 (-1.45, 0.34)		-1.26 (-1.80, -0.73)	
p-value [3]		0.220		<0.0001	

Spots Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	40	50	97	
Mean (StdDev)	5.40 (3.283)	3.33 (2.501)	5.03 (2.972)	3.77 (2.619)	
Median	5.07	3.00	5.11	3.27	
Min, Max	0.0, 10.0	0.0, 9.3	0.0, 10.0	0.0, 9.9	
C5D1 CFB					
n	17	40	50	95	
LS Mean (StdErr) [2]	-0.42 (0.411)	-0.95 (0.282)	-0.32 (0.265)	-1.69 (0.209)	
95% CI [2]	-1.25, 0.40	-1.52, -0.39	-0.84, 0.21	-2.10, -1.27	
Difference (95% CI) in CFB [2]		-0.53 (-1.46, 0.40)		-1.37 (-1.95, -0.80)	
p-value [3]		0.259		<0.0001	

Spots Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	17	40	49	96	
Mean (StdDev)	5.46 (3.168)	3.09 (2.239)	5.10 (3.028)	3.65 (2.713)	
Median	5.25	3.00	5.00	3.25	
Min, Max	0.0, 10.0	0.0, 7.3	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	17	40	49	94	
LS Mean (StdErr) [2]	-0.37 (0.423)	-1.20 (0.292)	-0.18 (0.325)	-1.65 (0.257)	
95% CI [2]	-1.22, 0.48	-1.79, -0.62	-0.82, 0.46	-2.16, -1.14	
Difference (95% CI) in CFB [2]		-0.83 (-1.79, 0.13)		-1.47 (-2.18, -0.76)	
p-value [3]		0.088		<0.0001	

Spots Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	17	40	49	93	
Mean (StdDev)	5.52 (3.285)	3.18 (2.325)	5.13 (2.894)	3.60 (2.799)	
Median	5.71	3.00	5.00	3.17	
Min, Max	0.0, 10.0	0.0, 7.0	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	17	40	49	91	
LS Mean (StdErr) [2]	-0.37 (0.425)	-1.17 (0.292)	-0.30 (0.330)	-1.77 (0.263)	
95% CI [2]	-1.22, 0.48	-1.76, -0.59	-0.95, 0.35	-2.29, -1.25	
Difference (95% CI) in CFB [2]		-0.80 (-1.77, 0.16)		-1.47 (-2.19, -0.75)	
Hedges'G (95% CI) in CFB		-0.44 (-1.04, 0.13)		-0.60 (-0.97, -0.25)	
p-value [3]		0.101		<0.0001	
					0.343

Itching Severity					
	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	17	41	54	98	
Mean (StdDev)	6.23 (2.889)	4.74 (2.625)	5.54 (2.765)	5.30 (2.872)	
Median	7.00	4.43	5.77	5.82	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	

Itching Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	17	40	54	97	
Mean (StdDev)	5.08 (2.922)	3.93 (2.394)	5.07 (2.794)	4.17 (2.542)	
Median	6.14	4.00	5.44	4.43	
Min, Max	0.0, 10.0	0.0, 9.9	0.0, 9.8	0.0, 9.6	
C2D1 CFB					
n	17	40	54	95	
LS Mean (StdErr) [2]	-1.29 (0.422)	-0.98 (0.290)	-0.40 (0.236)	-1.09 (0.197)	
95% CI [2]	-2.14, -0.45	-1.57, -0.40	-0.86, 0.07	-1.48, -0.70	
Difference (95% CI) in CFB [2]		0.31 (-0.65, 1.27)		-0.70 (-1.22, -0.18)	
p-value [3]		0.517		0.009	

Itching Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	40	54	95	
Mean (StdDev)	4.87 (3.228)	3.27 (2.273)	4.75 (2.707)	3.59 (2.578)	
Median	5.92	3.04	4.60	3.36	
Min, Max	0.0, 10.0	0.0, 8.2	0.0, 9.9	0.0, 9.7	
C3D1 CFB					
n	17	40	54	93	
LS Mean (StdErr) [2]	-1.37 (0.503)	-1.52 (0.346)	-0.60 (0.293)	-1.54 (0.245)	
95% CI [2]	-2.38, -0.36	-2.22, -0.83	-1.18, -0.02	-2.02, -1.05	
Difference (95% CI) in CFB [2]		-0.15 (-1.29, 0.99)		-0.93 (-1.58, -0.29)	
p-value [3]		0.792		0.005	

Itching Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	17	40	51	95	
Mean (StdDev)	4.59 (3.072)	3.17 (2.359)	4.71 (2.835)	3.32 (2.676)	
Median	4.29	2.75	5.14	3.07	
Min, Max	0.0, 10.0	0.0, 9.1	0.0, 9.8	0.0, 10.0	
C4D1 CFB					
n	17	40	51	93	
LS Mean (StdErr) [2]	-1.64 (0.595)	-1.61 (0.410)	-0.74 (0.345)	-1.90 (0.281)	
95% CI [2]	-2.83, -0.44	-2.43, -0.79	-1.42, -0.06	-2.46, -1.35	
Difference (95% CI) in CFB [2]		0.02 (-1.33, 1.38)		-1.16 (-1.91, -0.42)	
p-value [3]		0.971		0.003	

Itching Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	40	50	97	
Mean (StdDev)	4.87 (3.066)	3.05 (2.241)	4.73 (2.695)	3.04 (2.644)	
Median	4.64	2.72	4.73	2.79	
Min, Max	0.0, 10.0	0.0, 8.3	0.0, 10.0	0.0, 10.0	
C5D1 CFB					
n	17	40	50	95	
LS Mean (StdErr) [2]	-1.29 (0.622)	-1.67 (0.427)	-0.69 (0.355)	-2.09 (0.281)	
95% CI [2]	-2.54, -0.05	-2.53, -0.81	-1.39, 0.01	-2.65, -1.54	
Difference (95% CI) in CFB [2]		-0.38 (-1.79, 1.04)		-1.40 (-2.17, -0.63)	
p-value [3]		0.595		<0.001	

Itching Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	17	40	49	96	
Mean (StdDev)	5.08 (2.799)	3.00 (1.986)	4.59 (2.754)	3.01 (2.729)	
Median	5.69	2.61	4.07	2.68	
Min, Max	0.0, 10.0	0.0, 7.6	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	17	40	49	94	
LS Mean (StdErr) [2]	-1.07 (0.597)	-1.78 (0.411)	-0.87 (0.378)	-2.18 (0.299)	
95% CI [2]	-2.26, 0.13	-2.60, -0.95	-1.62, -0.12	-2.77, -1.59	
Difference (95% CI) in CFB [2]		-0.71 (-2.07, 0.65)		-1.31 (-2.14, -0.49)	
p-value [3]		0.299		0.002	

Itching Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	17	40	49	93	
Mean (StdDev)	5.16 (2.801)	3.06 (2.128)	4.73 (2.612)	2.94 (2.669)	
Median	5.85	2.75	4.75	2.64	
Min, Max	0.0, 10.0	0.0, 7.5	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	17	40	49	91	
LS Mean (StdErr) [2]	-1.04 (0.600)	-1.71 (0.412)	-0.84 (0.393)	-2.27 (0.314)	
95% CI [2]	-2.25, 0.16	-2.54, -0.89	-1.62, -0.06	-2.89, -1.65	
Difference (95% CI) in CFB [2]		-0.67 (-2.03, 0.69)		-1.43 (-2.29, -0.58)	
Hedges'G (95% CI) in CFB		-0.26 (-0.85, 0.31)		-0.49 (-0.85, -0.14)	
p-value [3]		0.327		0.001	
					0.361

Flushing Severity					
	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	17	41	54	98	
Mean (StdDev)	5.45 (2.518)	4.62 (2.469)	5.80 (2.718)	5.26 (2.539)	
Median	5.57	4.79	5.67	5.64	
Min, Max	0.5, 10.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	

Flushing Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	17	40	54	97	
Mean (StdDev)	4.85 (2.496)	4.16 (2.482)	5.27 (2.802)	4.48 (2.551)	
Median	4.64	4.07	4.89	4.79	
Min, Max	0.1, 9.2	0.0, 8.2	0.0, 10.0	0.0, 10.0	
C2D1 CFB					
n	17	40	54	95	
LS Mean (StdErr) [2]	-0.71 (0.349)	-0.59 (0.240)	-0.47 (0.231)	-0.75 (0.193)	
95% CI [2]	-1.41, -0.01	-1.07, -0.11	-0.93, -0.02	-1.13, -0.37	
Difference (95% CI) in CFB [2]		0.12 (-0.67, 0.91)		-0.28 (-0.78, 0.23)	
p-value [3]		0.766		0.283	

Flushing Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	40	54	95	
Mean (StdDev)	4.54 (2.745)	3.58 (2.437)	5.12 (2.917)	4.06 (2.509)	
Median	4.92	3.21	5.13	4.17	
Min, Max	0.0, 8.9	0.0, 8.8	0.0, 10.0	0.0, 10.0	
C3D1 CFB					
n	17	40	54	93	
LS Mean (StdErr) [2]	-0.91 (0.405)	-1.08 (0.278)	-0.53 (0.281)	-1.08 (0.236)	
95% CI [2]	-1.72, -0.10	-1.63, -0.52	-1.09, 0.02	-1.54, -0.61	
Difference (95% CI) in CFB [2]		-0.16 (-1.08, 0.76)		-0.55 (-1.17, 0.07)	
p-value [3]		0.723		0.083	

Flushing Severity					
	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	17	40	51	95	
Mean (StdDev)	4.15 (2.709)	3.40 (2.571)	5.25 (2.916)	3.84 (2.499)	
Median	3.86	3.00	5.57	3.77	
Min, Max	0.2, 9.7	0.0, 8.4	0.0, 10.0	0.0, 10.0	
C4D1 CFB					
n	17	40	51	93	
LS Mean (StdErr) [2]	-1.26 (0.455)	-1.21 (0.313)	-0.48 (0.326)	-1.38 (0.266)	
95% CI [2]	-2.17, -0.35	-1.84, -0.59	-1.12, 0.17	-1.90, -0.85	
Difference (95% CI) in CFB [2]		0.05 (-0.99, 1.08)		-0.90 (-1.61, -0.19)	
p-value [3]		0.929		0.013	

Flushing Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	40	50	97	
Mean (StdDev)	4.24 (2.762)	3.28 (2.577)	5.20 (2.965)	3.72 (2.480)	
Median	4.00	3.04	5.45	3.79	
Min, Max	0.4, 9.9	0.0, 9.0	0.0, 10.0	0.0, 9.8	
C5D1 CFB					
n	17	40	50	95	
LS Mean (StdErr) [2]	-1.18 (0.462)	-1.35 (0.318)	-0.57 (0.371)	-1.55 (0.293)	
95% CI [2]	-2.11, -0.26	-1.99, -0.71	-1.30, 0.16	-2.13, -0.97	
Difference (95% CI) in CFB [2]		-0.17 (-1.22, 0.88)		-0.98 (-1.79, -0.18)	
p-value [3]		0.753		0.017	

Flushing Severity					
	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	17	40	49	96	
Mean (StdDev)	4.37 (2.695)	3.27 (2.503)	5.00 (3.023)	3.50 (2.544)	
Median	3.86	2.76	5.00	3.30	
Min, Max	0.3, 9.6	0.0, 9.0	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	17	40	49	94	
LS Mean (StdErr) [2]	-1.10 (0.469)	-1.38 (0.323)	-0.78 (0.382)	-1.72 (0.303)	
95% CI [2]	-2.04, -0.16	-2.03, -0.74	-1.53, -0.02	-2.32, -1.12	
Difference (95% CI) in CFB [2]		-0.29 (-1.35, 0.78)		-0.95 (-1.78, -0.11)	
p-value [3]		0.592		0.026	

Flushing Severity

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	17	40	49	93	
Mean (StdDev)	4.50 (2.689)	3.30 (2.497)	5.06 (2.953)	3.24 (2.493)	
Median	4.75	2.71	4.54	3.08	
Min, Max	0.4, 10.0	0.0, 8.9	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	17	40	49	91	
LS Mean (StdErr) [2]	-0.93 (0.497)	-1.35 (0.342)	-0.78 (0.393)	-1.85 (0.314)	
95% CI [2]	-1.93, 0.06	-2.04, -0.67	-1.56, -0.00	-2.47, -1.23	
Difference (95% CI) in CFB [2]		-0.42 (-1.55, 0.71)		-1.07 (-1.93, -0.22)	
Hedges'G (95% CI) in CFB		-0.19 (-0.78, 0.38)		-0.37 (-0.73, -0.02)	
p-value [3]		0.458		0.014	
					0.407

Fatigue Severity					
	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	17	41	54	98	
Mean (StdDev)	6.67 (2.122)	5.69 (1.967)	6.73 (1.997)	7.05 (2.060)	
Median	6.43	5.79	6.75	7.37	
Min, Max	2.7, 10.0	0.5, 9.4	0.0, 10.0	0.1, 10.0	

Fatigue Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	17	40	54	97	
Mean (StdDev)	6.10 (2.199)	5.25 (2.091)	6.36 (1.921)	6.26 (2.343)	
Median	6.29	5.46	6.30	6.43	
Min, Max	3.0, 9.9	0.1, 9.1	2.3, 10.0	0.1, 10.0	
C2D1 CFB					
n	17	40	54	95	
LS Mean (StdErr) [2]	-0.63 (0.241)	-0.55 (0.165)	-0.41 (0.199)	-0.84 (0.166)	
95% CI [2]	-1.11, -0.15	-0.88, -0.22	-0.80, -0.02	-1.16, -0.51	
Difference (95% CI) in CFB [2]		0.08 (-0.47, 0.62)		-0.42 (-0.86, 0.01)	
p-value [3]		0.778		0.057	

Fatigue Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	40	54	95	
Mean (StdDev)	5.54 (2.593)	4.95 (2.013)	6.04 (2.253)	5.81 (2.444)	
Median	4.50	5.13	6.00	5.83	
Min, Max	1.6, 9.9	0.7, 9.0	0.3, 10.0	0.2, 10.0	
C3D1 CFB					
n	17	40	54	93	
LS Mean (StdErr) [2]	-1.28 (0.324)	-0.94 (0.223)	-0.68 (0.252)	-1.21 (0.211)	
95% CI [2]	-1.93, -0.63	-1.38, -0.49	-1.18, -0.18	-1.62, -0.79	
Difference (95% CI) in CFB [2]		0.34 (-0.39, 1.08)		-0.53 (-1.08, 0.03)	
p-value [3]		0.353		0.063	

Fatigue Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	17	40	51	95	
Mean (StdDev)	4.99 (2.947)	4.78 (2.144)	5.92 (2.231)	5.49 (2.600)	
Median	4.29	4.93	6.00	5.57	
Min, Max	0.2, 9.9	0.0, 9.1	1.3, 10.0	0.0, 10.0	
C4D1 CFB					
n	17	40	51	93	
LS Mean (StdErr) [2]	-1.78 (0.397)	-1.06 (0.273)	-0.83 (0.310)	-1.60 (0.253)	
95% CI [2]	-2.58, -0.99	-1.61, -0.52	-1.45, -0.22	-2.10, -1.10	
Difference (95% CI) in CFB [2]		0.72 (-0.18, 1.62)		-0.77 (-1.44, -0.09)	
p-value [3]		0.116		0.026	

Fatigue Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	40	50	97	
Mean (StdDev)	5.06 (2.838)	4.53 (2.105)	5.73 (2.292)	5.51 (2.562)	
Median	5.07	4.40	5.61	5.58	
Min, Max	0.6, 9.9	0.0, 9.0	1.2, 10.0	0.0, 10.0	
C5D1 CFB					
n	17	40	50	95	
LS Mean (StdErr) [2]	-1.47 (0.420)	-1.09 (0.289)	-1.04 (0.323)	-1.57 (0.256)	
95% CI [2]	-2.31, -0.62	-1.67, -0.51	-1.68, -0.40	-2.08, -1.07	
Difference (95% CI) in CFB [2]		0.38 (-0.58, 1.33)		-0.53 (-1.23, 0.17)	
p-value [3]		0.432		0.137	

Fatigue Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	17	40	49	96	
Mean (StdDev)	5.04 (2.759)	4.33 (2.172)	5.81 (2.317)	5.30 (2.782)	
Median	4.83	4.48	5.92	5.30	
Min, Max	1.1, 9.6	0.0, 9.4	0.4, 10.0	0.0, 10.0	
C6D1 CFB					
n	17	40	49	94	
LS Mean (StdErr) [2]	-1.60 (0.453)	-1.33 (0.312)	-0.81 (0.350)	-1.68 (0.277)	
95% CI [2]	-2.51, -0.69	-1.96, -0.71	-1.50, -0.12	-2.23, -1.13	
Difference (95% CI) in CFB [2]		0.26 (-0.76, 1.29)		-0.87 (-1.64, -0.11)	
p-value [3]		0.609		0.026	

Fatigue Severity

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	17	40	49	93	
Mean (StdDev)	4.89 (2.726)	4.50 (2.085)	5.82 (2.421)	5.05 (2.761)	
Median	4.64	4.50	5.78	5.14	
Min, Max	0.4, 10.0	0.0, 9.0	0.2, 10.0	0.0, 10.0	
C7D1 CFB					
n	17	40	49	91	
LS Mean (StdErr) [2]	-1.74 (0.471)	-1.22 (0.324)	-0.83 (0.351)	-1.90 (0.280)	
95% CI [2]	-2.68, -0.79	-1.87, -0.57	-1.52, -0.14	-2.45, -1.35	
Difference (95% CI) in CFB [2]		0.52 (-0.55, 1.59)		-1.07 (-1.84, -0.30)	
Hedges'G (95% CI) in CFB		0.25 (-0.32, 0.84)		-0.41 (-0.77, -0.06)	
p-value [3]		0.337		0.007	
					0.025

Dizziness Severity					
	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	17	41	54	98	
Mean (StdDev)	4.36 (3.116)	2.78 (2.677)	3.33 (2.625)	4.01 (2.882)	
Median	3.36	1.50	2.75	3.93	
Min, Max	0.0, 8.4	0.0, 8.9	0.0, 9.3	0.0, 10.0	

Dizziness Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	17	40	54	97	
Mean (StdDev)	3.98 (2.786)	2.69 (2.593)	2.85 (2.564)	3.26 (2.688)	
Median	3.43	2.08	2.29	3.00	
Min, Max	0.0, 8.7	0.0, 8.1	0.0, 8.4	0.0, 10.0	
C2D1 CFB					
n	17	40	54	95	
LS Mean (StdErr) [2]	-0.47 (0.286)	-0.21 (0.197)	-0.38 (0.214)	-0.68 (0.179)	
95% CI [2]	-1.04, 0.10	-0.61, 0.18	-0.81, 0.04	-1.04, -0.33	
Difference (95% CI) in CFB [2]		0.26 (-0.39, 0.91)		-0.30 (-0.77, 0.17)	
p-value [3]		0.430		0.209	

Dizziness Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	40	54	95	
Mean (StdDev)	3.54 (2.903)	2.45 (2.349)	2.52 (2.420)	2.89 (2.786)	
Median	2.54	1.93	1.92	2.36	
Min, Max	0.0, 8.0	0.0, 8.1	0.0, 8.1	0.0, 10.0	
C3D1 CFB					
n	17	40	54	93	
LS Mean (StdErr) [2]	-0.93 (0.311)	-0.50 (0.214)	-0.67 (0.256)	-1.03 (0.215)	
95% CI [2]	-1.56, -0.31	-0.93, -0.08	-1.18, -0.17	-1.45, -0.60	
Difference (95% CI) in CFB [2]		0.43 (-0.28, 1.13)		-0.35 (-0.92, 0.21)	
p-value [3]		0.229		0.218	

Dizziness Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	17	40	51	95	
Mean (StdDev)	3.61 (3.133)	2.48 (2.464)	2.67 (2.447)	2.76 (2.810)	
Median	2.86	1.81	2.29	1.93	
Min, Max	0.0, 9.9	0.0, 8.5	0.0, 8.1	0.0, 10.0	
C4D1 CFB					
n	17	40	51	93	
LS Mean (StdErr) [2]	-0.91 (0.358)	-0.51 (0.246)	-0.55 (0.311)	-1.21 (0.254)	
95% CI [2]	-1.62, -0.19	-1.00, -0.02	-1.17, 0.06	-1.71, -0.71	
Difference (95% CI) in CFB [2]		0.40 (-0.42, 1.21)		-0.66 (-1.33, 0.02)	
p-value [3]		0.332		0.055	

Dizziness Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	40	50	97	
Mean (StdDev)	3.65 (3.102)	2.31 (2.399)	2.68 (2.385)	2.64 (2.722)	
Median	2.57	1.79	1.96	1.80	
Min, Max	0.0, 9.6	0.0, 8.0	0.0, 7.8	0.0, 10.0	
C5D1 CFB					
n	17	40	50	95	
LS Mean (StdErr) [2]	-0.69 (0.347)	-0.51 (0.239)	-0.53 (0.311)	-1.27 (0.246)	
95% CI [2]	-1.38, 0.01	-0.99, -0.03	-1.14, 0.09	-1.75, -0.78	
Difference (95% CI) in CFB [2]		0.17 (-0.61, 0.96)		-0.74 (-1.41, -0.06)	
p-value [3]		0.658		0.033	

Dizziness Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	17	40	49	96	
Mean (StdDev)	3.38 (3.112)	2.12 (2.158)	2.46 (2.378)	2.38 (2.658)	
Median	2.50	1.68	1.71	1.59	
Min, Max	0.0, 8.6	0.0, 7.6	0.0, 8.3	0.0, 10.0	
C6D1 CFB					
n	17	40	49	94	
LS Mean (StdErr) [2]	-1.08 (0.380)	-0.76 (0.262)	-0.73 (0.330)	-1.49 (0.262)	
95% CI [2]	-1.85, -0.32	-1.29, -0.24	-1.39, -0.08	-2.01, -0.97	
Difference (95% CI) in CFB [2]		0.32 (-0.54, 1.19)		-0.75 (-1.48, -0.03)	
p-value [3]		0.457		0.040	

Dizziness Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	17	40	49	93	
Mean (StdDev)	3.54 (3.180)	2.17 (2.192)	2.44 (2.396)	2.39 (2.688)	
Median	2.21	1.56	1.79	1.58	
Min, Max	0.0, 10.0	0.0, 7.5	0.0, 8.8	0.0, 10.0	
C7D1 CFB					
n	17	40	49	91	
LS Mean (StdErr) [2]	-0.95 (0.355)	-0.81 (0.244)	-0.77 (0.351)	-1.42 (0.280)	
95% CI [2]	-1.67, -0.24	-1.30, -0.32	-1.47, -0.08	-1.98, -0.87	
Difference (95% CI) in CFB [2]		0.15 (-0.66, 0.95)		-0.65 (-1.41, 0.12)	
Hedges'G (95% CI) in CFB		0.09 (-0.48, 0.68)		-0.25 (-0.60, 0.10)	
p-value [3]		0.717		0.096	
					0.240

Brain Fog Severity					
	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	17	41	54	98	
Mean (StdDev)	4.69 (3.104)	4.65 (2.189)	5.14 (2.643)	5.68 (2.574)	
Median	5.00	4.57	5.22	5.95	
Min, Max	0.0, 9.1	0.0, 10.0	0.0, 10.0	0.0, 10.0	

Brain Fog Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	17	40	54	97	
Mean (StdDev)	4.20 (2.904)	4.32 (2.182)	4.64 (2.601)	4.90 (2.856)	
Median	3.64	4.21	4.30	5.07	
Min, Max	0.0, 9.5	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C2D1 CFB					
n	17	40	54	95	
LS Mean (StdErr) [2]	-0.62 (0.256)	-0.51 (0.176)	-0.44 (0.183)	-0.72 (0.153)	
95% CI [2]	-1.13, -0.10	-0.86, -0.16	-0.80, -0.07	-1.03, -0.42	
Difference (95% CI) in CFB [2]		0.11 (-0.47, 0.69)		-0.29 (-0.69, 0.11)	
p-value [3]		0.713		0.157	

Brain Fog Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	40	54	95	
Mean (StdDev)	3.65 (2.935)	4.01 (2.147)	4.51 (2.651)	4.57 (2.925)	
Median	3.21	4.00	4.18	4.64	
Min, Max	0.0, 8.8	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C3D1 CFB					
n	17	40	54	93	
LS Mean (StdErr) [2]	-1.21 (0.261)	-0.86 (0.180)	-0.52 (0.226)	-1.04 (0.190)	
95% CI [2]	-1.73, -0.69	-1.22, -0.50	-0.96, -0.07	-1.41, -0.66	
Difference (95% CI) in CFB [2]		0.35 (-0.24, 0.95)		-0.52 (-1.02, -0.02)	
p-value [3]		0.239		0.041	

Brain Fog Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	17	40	51	95	
Mean (StdDev)	3.53 (2.972)	3.85 (2.241)	4.29 (2.732)	4.32 (3.052)	
Median	2.79	3.79	4.29	4.25	
Min, Max	0.0, 9.9	0.0, 9.9	0.0, 10.0	0.0, 10.0	
C4D1 CFB					
n	17	40	51	93	
LS Mean (StdErr) [2]	-1.30 (0.304)	-0.99 (0.209)	-0.78 (0.290)	-1.30 (0.236)	
95% CI [2]	-1.91, -0.69	-1.41, -0.57	-1.35, -0.20	-1.77, -0.84	
Difference (95% CI) in CFB [2]		0.31 (-0.38, 1.00)		-0.53 (-1.16, 0.10)	
p-value [3]		0.370		0.099	

Brain Fog Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	40	50	97	
Mean (StdDev)	3.44 (3.081)	3.65 (2.308)	4.07 (2.695)	4.38 (3.033)	
Median	2.93	3.50	3.64	4.64	
Min, Max	0.0, 9.9	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C5D1 CFB					
n	17	40	50	95	
LS Mean (StdErr) [2]	-1.25 (0.337)	-1.06 (0.232)	-0.90 (0.317)	-1.15 (0.251)	
95% CI [2]	-1.93, -0.57	-1.53, -0.60	-1.53, -0.27	-1.64, -0.65	
Difference (95% CI) in CFB [2]		0.19 (-0.58, 0.95)		-0.25 (-0.93, 0.44)	
p-value [3]		0.627		0.479	

Brain Fog Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	17	40	49	96	
Mean (StdDev)	3.54 (3.089)	3.72 (2.275)	4.12 (2.653)	4.11 (3.107)	
Median	2.92	3.58	3.86	3.68	
Min, Max	0.0, 9.6	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	17	40	49	94	
LS Mean (StdErr) [2]	-1.26 (0.326)	-1.07 (0.224)	-0.75 (0.311)	-1.38 (0.247)	
95% CI [2]	-1.91, -0.61	-1.52, -0.62	-1.36, -0.13	-1.87, -0.89	
Difference (95% CI) in CFB [2]		0.19 (-0.55, 0.93)		-0.63 (-1.31, 0.05)	
p-value [3]		0.613		0.067	

Brain Fog Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	17	40	49	93	
Mean (StdDev)	3.43 (2.987)	3.68 (2.306)	4.20 (2.815)	4.04 (3.157)	
Median	2.92	3.76	3.79	3.64	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	17	40	49	91	
LS Mean (StdErr) [2]	-1.39 (0.337)	-1.16 (0.232)	-0.70 (0.328)	-1.41 (0.262)	
95% CI [2]	-2.07, -0.71	-1.63, -0.70	-1.35, -0.05	-1.93, -0.89	
Difference (95% CI) in CFB [2]		0.23 (-0.54, 1.00)		-0.71 (-1.43, 0.01)	
Hedges'G (95% CI) in CFB		0.16 (-0.42, 0.74)		-0.29 (-0.65, 0.06)	
p-value [3]		0.551		0.052	
					0.139

Headache Severity					
	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	17	41	54	98	
Mean (StdDev)	4.15 (2.824)	3.14 (2.358)	4.08 (2.701)	4.39 (2.556)	
Median	4.50	3.00	3.96	4.00	
Min, Max	0.0, 8.4	0.0, 7.9	0.3, 9.9	0.0, 9.9	

Headache Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	17	40	54	97	
Mean (StdDev)	3.60 (2.419)	2.75 (2.289)	3.83 (2.666)	3.77 (2.440)	
Median	4.09	2.29	3.29	3.64	
Min, Max	0.0, 8.1	0.0, 8.1	0.1, 9.1	0.0, 10.0	
C2D1 CFB					
n	17	40	54	95	
LS Mean (StdErr) [2]	-0.66 (0.216)	-0.51 (0.149)	-0.23 (0.206)	-0.62 (0.172)	
95% CI [2]	-1.10, -0.23	-0.81, -0.22	-0.64, 0.18	-0.96, -0.28	
Difference (95% CI) in CFB [2]		0.15 (-0.34, 0.64)		-0.39 (-0.84, 0.06)	
p-value [3]		0.543		0.093	

Headache Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	40	54	95	
Mean (StdDev)	3.05 (2.434)	2.53 (2.129)	3.52 (2.619)	3.41 (2.470)	
Median	2.69	2.32	3.11	3.07	
Min, Max	0.0, 8.1	0.0, 7.7	0.0, 9.1	0.0, 10.0	
C3D1 CFB					
n	17	40	54	93	
LS Mean (StdErr) [2]	-1.21 (0.375)	-0.74 (0.258)	-0.51 (0.248)	-0.95 (0.208)	
95% CI [2]	-1.96, -0.46	-1.26, -0.23	-1.00, -0.02	-1.36, -0.54	
Difference (95% CI) in CFB [2]		0.47 (-0.38, 1.32)		-0.44 (-0.99, 0.11)	
p-value [3]		0.274		0.114	

Headache Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	17	40	51	95	
Mean (StdDev)	3.25 (2.422)	2.52 (2.087)	3.54 (2.529)	3.20 (2.472)	
Median	3.15	2.07	3.14	2.92	
Min, Max	0.0, 8.1	0.0, 7.7	0.0, 8.4	0.0, 9.9	
C4D1 CFB					
n	17	40	51	93	
LS Mean (StdErr) [2]	-0.98 (0.362)	-0.73 (0.249)	-0.65 (0.289)	-1.28 (0.236)	
95% CI [2]	-1.71, -0.26	-1.23, -0.23	-1.22, -0.08	-1.75, -0.82	
Difference (95% CI) in CFB [2]		0.25 (-0.57, 1.07)		-0.63 (-1.26, -0.01)	
p-value [3]		0.541		0.047	

Headache Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	40	50	97	
Mean (StdDev)	3.05 (2.525)	2.25 (2.019)	3.54 (2.479)	3.17 (2.460)	
Median	2.79	2.07	3.10	2.85	
Min, Max	0.0, 9.0	0.0, 7.1	0.0, 9.1	0.0, 10.0	
C5D1 CFB					
n	17	40	50	95	
LS Mean (StdErr) [2]	-1.16 (0.335)	-0.97 (0.230)	-0.73 (0.295)	-1.35 (0.234)	
95% CI [2]	-1.83, -0.49	-1.44, -0.51	-1.32, -0.15	-1.81, -0.89	
Difference (95% CI) in CFB [2]		0.18 (-0.58, 0.94)		-0.61 (-1.25, 0.03)	
p-value [3]		0.631		0.060	

Headache Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	17	40	49	96	
Mean (StdDev)	2.86 (2.412)	2.08 (1.943)	3.23 (2.524)	2.93 (2.541)	
Median	2.43	1.52	2.86	2.56	
Min, Max	0.0, 8.9	0.0, 7.1	0.0, 8.3	0.0, 10.0	
C6D1 CFB					
n	17	40	49	94	
LS Mean (StdErr) [2]	-1.45 (0.369)	-1.22 (0.254)	-0.81 (0.301)	-1.48 (0.239)	
95% CI [2]	-2.19, -0.71	-1.73, -0.71	-1.41, -0.21	-1.95, -1.00	
Difference (95% CI) in CFB [2]		0.23 (-0.61, 1.06)		-0.67 (-1.32, -0.01)	
p-value [3]		0.589		0.047	

Headache Severity

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	17	40	49	93	
Mean (StdDev)	2.98 (2.520)	2.17 (2.079)	3.30 (2.625)	2.87 (2.458)	
Median	2.36	1.72	2.86	2.54	
Min, Max	0.0, 8.9	0.0, 7.4	0.0, 7.9	0.0, 10.0	
C7D1 CFB					
n	17	40	49	91	
LS Mean (StdErr) [2]	-1.25 (0.414)	-1.08 (0.285)	-0.75 (0.297)	-1.49 (0.237)	
95% CI [2]	-2.08, -0.42	-1.66, -0.51	-1.34, -0.16	-1.96, -1.02	
Difference (95% CI) in CFB [2]		0.17 (-0.77, 1.11)		-0.74 (-1.39, -0.09)	
Hedges'G (95% CI) in CFB		0.09 (-0.48, 0.68)		-0.33 (-0.69, 0.01)	
p-value [3]		0.719		0.026	
					0.130

Diarrhea Count	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	17	41	54	98	
Mean (StdDev)	1.68 (1.834)	1.48 (1.383)	1.44 (1.357)	1.42 (1.751)	
Median	1.14	1.07	1.15	0.86	
Min, Max	0.0, 7.2	0.0, 5.6	0.0, 6.1	0.0, 12.2	

Diarrhea Count	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	17	40	54	97	
Mean (StdDev)	1.40 (1.340)	1.20 (1.148)	1.18 (1.263)	1.06 (1.512)	
Median	1.00	0.93	0.57	0.50	
Min, Max	0.0, 3.8	0.0, 4.3	0.0, 4.9	0.0, 10.7	
C2D1 CFB					
n	17	40	54	95	
LS Mean (StdErr) [2]	-0.31 (0.219)	-0.32 (0.151)	-0.36 (0.126)	-0.50 (0.106)	
95% CI [2]	-0.75, 0.13	-0.62, -0.02	-0.61, -0.11	-0.71, -0.29	
Difference (95% CI) in CFB [2]		-0.01 (-0.51, 0.49)		-0.14 (-0.42, 0.14)	
p-value [3]		0.964		0.312	

Diarrhea Count	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	40	54	95	
Mean (StdDev)	1.02 (1.184)	1.24 (1.410)	1.17 (1.167)	0.88 (1.062)	
Median	0.31	0.92	0.79	0.50	
Min, Max	0.0, 3.4	0.0, 5.8	0.0, 4.4	0.0, 5.6	
C3D1 CFB					
n	17	40	54	93	
LS Mean (StdErr) [2]	-0.62 (0.217)	-0.22 (0.150)	-0.46 (0.174)	-0.76 (0.146)	
95% CI [2]	-1.05, -0.18	-0.52, 0.08	-0.80, -0.11	-1.05, -0.47	
Difference (95% CI) in CFB [2]		0.40 (-0.09, 0.90)		-0.30 (-0.69, 0.08)	
p-value [3]		0.108		0.122	

Diarrhea Count	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	17	40	51	95	
Mean (StdDev)	1.18 (1.371)	1.02 (1.161)	1.10 (1.058)	0.98 (1.447)	
Median	0.71	0.74	0.77	0.36	
Min, Max	0.0, 4.8	0.0, 5.4	0.0, 4.3	0.0, 9.0	
C4D1 CFB					
n	17	40	51	93	
LS Mean (StdErr) [2]	-0.53 (0.220)	-0.50 (0.151)	-0.50 (0.173)	-0.58 (0.141)	
95% CI [2]	-0.97, -0.09	-0.80, -0.20	-0.84, -0.16	-0.86, -0.30	
Difference (95% CI) in CFB [2]		0.03 (-0.47, 0.53)		-0.08 (-0.46, 0.29)	
p-value [3]		0.919		0.666	

Diarrhea Count	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	40	50	97	
Mean (StdDev)	1.37 (1.427)	0.92 (1.034)	1.06 (1.099)	1.02 (1.575)	
Median	0.93	0.57	0.57	0.43	
Min, Max	0.0, 4.8	0.0, 4.6	0.0, 4.0	0.0, 9.6	
C5D1 CFB					
n	17	40	50	95	
LS Mean (StdErr) [2]	-0.32 (0.248)	-0.58 (0.171)	-0.56 (0.196)	-0.59 (0.155)	
95% CI [2]	-0.82, 0.18	-0.92, -0.24	-0.95, -0.17	-0.90, -0.28	
Difference (95% CI) in CFB [2]		-0.26 (-0.83, 0.30)		-0.03 (-0.46, 0.40)	
p-value [3]		0.351		0.890	

Diarrhea Count	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	17	40	49	96	
Mean (StdDev)	1.41 (1.801)	0.87 (0.887)	0.92 (1.016)	0.93 (1.418)	
Median	0.54	0.50	0.64	0.37	
Min, Max	0.0, 6.5	0.0, 3.3	0.0, 4.3	0.0, 9.0	
C6D1 CFB					
n	17	40	49	94	
LS Mean (StdErr) [2]	-0.28 (0.198)	-0.56 (0.136)	-0.59 (0.172)	-0.63 (0.136)	
95% CI [2]	-0.68, 0.12	-0.84, -0.29	-0.93, -0.25	-0.90, -0.36	
Difference (95% CI) in CFB [2]		-0.28 (-0.73, 0.17)		-0.03 (-0.41, 0.34)	
p-value [3]		0.216		0.861	

Diarrhea Count	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	17	40	49	93	
Mean (StdDev)	1.47 (1.704)	0.88 (1.038)	0.90 (1.007)	0.81 (1.132)	
Median	0.79	0.31	0.50	0.27	
Min, Max	0.0, 5.9	0.0, 4.0	0.0, 4.1	0.0, 4.8	
C7D1 CFB					
n	17	40	49	91	
LS Mean (StdErr) [2]	-0.24 (0.232)	-0.65 (0.159)	-0.55 (0.185)	-0.56 (0.148)	
95% CI [2]	-0.70, 0.23	-0.97, -0.33	-0.91, -0.18	-0.86, -0.27	
Difference (95% CI) in CFB [2]		-0.41 (-0.94, 0.11)		-0.02 (-0.42, 0.38)	
Hedges'G (95% CI) in CFB		-0.41 (-1.01, 0.16)		-0.01 (-0.36, 0.34)	
p-value [3]		0.122		0.924	
					0.288

Diarrhea Severity					
	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	17	41	54	98	
Mean (StdDev)	3.29 (2.653)	3.13 (2.266)	3.00 (2.615)	2.79 (2.453)	
Median	2.43	3.00	2.21	2.21	
Min, Max	0.0, 7.9	0.0, 8.5	0.0, 9.5	0.0, 9.5	

Diarrhea Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	17	40	54	97	
Mean (StdDev)	2.62 (2.144)	2.70 (2.370)	2.30 (2.474)	2.13 (2.313)	
Median	2.64	1.96	1.32	1.14	
Min, Max	0.0, 6.7	0.0, 8.2	0.0, 9.1	0.0, 8.9	
C2D1 CFB					
n	17	40	54	95	
LS Mean (StdErr) [2]	-0.54 (0.351)	-0.31 (0.242)	-0.63 (0.212)	-0.65 (0.177)	
95% CI [2]	-1.25, 0.16	-0.80, 0.17	-1.05, -0.21	-1.00, -0.30	
Difference (95% CI) in CFB [2]		0.23 (-0.57, 1.03)		-0.02 (-0.49, 0.44)	
p-value [3]		0.569		0.929	

Diarrhea Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	40	54	95	
Mean (StdDev)	2.09 (2.144)	2.68 (2.499)	2.29 (2.338)	1.84 (2.083)	
Median	1.50	2.46	1.46	1.00	
Min, Max	0.0, 6.9	0.0, 9.5	0.0, 8.7	0.0, 8.1	
C3D1 CFB					
n	17	40	54	93	
LS Mean (StdErr) [2]	-0.95 (0.434)	-0.23 (0.298)	-0.73 (0.252)	-1.01 (0.211)	
95% CI [2]	-1.82, -0.08	-0.82, 0.37	-1.22, -0.23	-1.43, -0.60	
Difference (95% CI) in CFB [2]		0.73 (-0.26, 1.71)		-0.29 (-0.84, 0.27)	
p-value [3]		0.144		0.307	

Diarrhea Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	17	40	51	95	
Mean (StdDev)	2.37 (2.302)	2.30 (2.193)	2.42 (2.385)	1.90 (2.295)	
Median	1.62	1.77	1.57	0.93	
Min, Max	0.0, 6.6	0.0, 7.5	0.0, 8.3	0.0, 8.9	
C4D1 CFB					
n	17	40	51	93	
LS Mean (StdErr) [2]	-0.80 (0.393)	-0.72 (0.271)	-0.60 (0.265)	-0.88 (0.216)	
95% CI [2]	-1.59, -0.01	-1.26, -0.17	-1.12, -0.07	-1.31, -0.45	
Difference (95% CI) in CFB [2]		0.08 (-0.81, 0.98)		-0.28 (-0.86, 0.30)	
p-value [3]		0.850		0.339	

Diarrhea Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	40	50	97	
Mean (StdDev)	2.70 (2.211)	2.12 (2.118)	2.29 (2.413)	1.88 (2.243)	
Median	2.23	1.38	1.04	1.00	
Min, Max	0.0, 7.3	0.0, 7.9	0.0, 8.5	0.0, 9.0	
C5D1 CFB					
n	17	40	50	95	
LS Mean (StdErr) [2]	-0.43 (0.445)	-0.86 (0.306)	-0.81 (0.298)	-0.98 (0.236)	
95% CI [2]	-1.32, 0.47	-1.48, -0.25	-1.40, -0.22	-1.45, -0.52	
Difference (95% CI) in CFB [2]		-0.44 (-1.45, 0.57)		-0.17 (-0.81, 0.48)	
p-value [3]		0.391		0.606	

Diarrhea Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	17	40	49	96	
Mean (StdDev)	2.42 (2.348)	2.15 (2.281)	2.11 (2.351)	1.68 (2.112)	
Median	1.36	1.50	1.29	0.93	
Min, Max	0.0, 6.8	0.0, 8.9	0.0, 8.6	0.0, 8.6	
C6D1 CFB					
n	17	40	49	94	
LS Mean (StdErr) [2]	-0.71 (0.455)	-0.78 (0.313)	-0.72 (0.271)	-1.03 (0.215)	
95% CI [2]	-1.62, 0.20	-1.41, -0.16	-1.26, -0.19	-1.46, -0.61	
Difference (95% CI) in CFB [2]		-0.07 (-1.11, 0.96)		-0.31 (-0.90, 0.28)	
p-value [3]		0.888		0.298	

Diarrhea Severity	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	17	40	49	93	
Mean (StdDev)	2.59 (2.361)	2.04 (2.195)	2.05 (2.460)	1.66 (2.184)	
Median	2.36	1.21	1.08	0.56	
Min, Max	0.0, 7.1	0.0, 8.7	0.0, 8.6	0.0, 8.4	
C7D1 CFB					
n	17	40	49	91	
LS Mean (StdErr) [2]	-0.55 (0.487)	-0.97 (0.335)	-0.79 (0.297)	-0.98 (0.237)	
95% CI [2]	-1.53, 0.43	-1.64, -0.30	-1.38, -0.20	-1.45, -0.51	
Difference (95% CI) in CFB [2]		-0.42 (-1.52, 0.69)		-0.19 (-0.84, 0.46)	
Hedges'G (95% CI) in CFB		-0.20 (-0.79, 0.38)		-0.09 (-0.44, 0.26)	
p-value [3]		0.453		0.560	
					0.717

Bone Pain Severity					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	33	58	38	81	
Mean (StdDev)	5.21 (2.757)	5.07 (2.840)	5.56 (2.156)	5.41 (2.410)	
Median	5.58	5.41	5.54	5.92	
Min, Max	0.0, 9.4	0.0, 10.0	1.1, 10.0	0.0, 10.0	

Bone Pain Severity					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	33	59	38	78	
Mean (StdDev)	4.46 (2.772)	4.56 (2.750)	5.12 (2.370)	4.53 (2.683)	
Median	5.21	4.46	4.73	4.00	
Min, Max	0.0, 9.0	0.0, 9.9	0.7, 10.0	0.0, 10.0	
C2D1 CFB					
n	33	57	38	78	
LS Mean (StdErr) [2]	-0.80 (0.239)	-0.67 (0.200)	-0.33 (0.214)	-0.74 (0.160)	
95% CI [2]	-1.28, -0.33	-1.07, -0.28	-0.75, 0.10	-1.06, -0.42	
Difference (95% CI) in CFB [2]		0.13 (-0.42, 0.67)		-0.41 (-0.89, 0.06)	
p-value [3]		0.645		0.085	

Bone Pain Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	33	58	38	77	
Mean (StdDev)	4.27 (2.868)	4.23 (2.800)	5.02 (2.481)	4.35 (2.727)	
Median	4.69	4.04	5.48	3.86	
Min, Max	0.0, 9.1	0.0, 10.0	1.0, 10.0	0.0, 10.0	
C3D1 CFB					
n	33	56	38	77	
LS Mean (StdErr) [2]	-1.02 (0.275)	-1.00 (0.230)	-0.44 (0.265)	-0.92 (0.198)	
95% CI [2]	-1.56, -0.47	-1.46, -0.54	-0.96, 0.09	-1.32, -0.53	
Difference (95% CI) in CFB [2]		0.01 (-0.61, 0.64)		-0.49 (-1.07, 0.10)	
p-value [3]		0.969		0.102	

Bone Pain Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	31	58	37	77	
Mean (StdDev)	4.25 (2.985)	4.22 (2.911)	5.07 (2.496)	4.34 (2.776)	
Median	4.07	4.11	5.14	3.71	
Min, Max	0.0, 8.6	0.0, 10.0	0.9, 9.8	0.0, 10.0	
C4D1 CFB					
n	31	56	37	77	
LS Mean (StdErr) [2]	-1.08 (0.328)	-1.03 (0.265)	-0.32 (0.314)	-0.81 (0.233)	
95% CI [2]	-1.73, -0.43	-1.56, -0.50	-0.94, 0.30	-1.27, -0.35	
Difference (95% CI) in CFB [2]		0.05 (-0.68, 0.78)		-0.49 (-1.18, 0.20)	
p-value [3]		0.884		0.165	

Bone Pain Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	30	59	37	78	
Mean (StdDev)	4.40 (3.056)	3.92 (2.835)	4.93 (2.448)	4.15 (2.838)	
Median	4.28	3.36	4.86	3.73	
Min, Max	0.0, 9.0	0.0, 10.0	0.9, 9.8	0.0, 10.0	
C5D1 CFB					
n	30	57	37	78	
LS Mean (StdErr) [2]	-0.81 (0.330)	-1.16 (0.257)	-0.39 (0.350)	-0.93 (0.259)	
95% CI [2]	-1.46, -0.15	-1.67, -0.65	-1.09, 0.30	-1.44, -0.41	
Difference (95% CI) in CFB [2]		-0.35 (-1.09, 0.38)		-0.53 (-1.30, 0.24)	
p-value [3]		0.343		0.173	

Bone Pain Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	29	58	37	78	
Mean (StdDev)	4.22 (3.013)	3.88 (2.759)	5.00 (2.445)	3.95 (2.757)	
Median	4.54	3.37	5.46	3.75	
Min, Max	0.0, 9.1	0.0, 10.0	0.8, 9.6	0.0, 10.0	
C6D1 CFB					
n	29	56	37	78	
LS Mean (StdErr) [2]	-0.76 (0.370)	-1.11 (0.288)	-0.26 (0.342)	-1.11 (0.252)	
95% CI [2]	-1.49, -0.02	-1.68, -0.54	-0.94, 0.41	-1.61, -0.61	
Difference (95% CI) in CFB [2]		-0.36 (-1.19, 0.47)		-0.84 (-1.59, -0.09)	
p-value [3]		0.396		0.029	

Bone Pain Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	30	57	36	76	
Mean (StdDev)	4.24 (3.156)	3.84 (2.796)	4.92 (2.247)	3.87 (2.781)	
Median	4.64	3.50	5.26	3.36	
Min, Max	0.0, 9.3	0.0, 10.0	0.9, 9.4	0.0, 10.0	
C7D1 CFB					
n	30	55	36	76	
LS Mean (StdErr) [2]	-0.92 (0.372)	-1.19 (0.298)	-0.35 (0.355)	-1.15 (0.260)	
95% CI [2]	-1.66, -0.18	-1.78, -0.60	-1.06, 0.35	-1.67, -0.64	
Difference (95% CI) in CFB [2]		-0.27 (-1.10, 0.57)		-0.80 (-1.58, -0.02)	
Hedges'G (95% CI) in CFB		-0.12 (-0.58, 0.33)		-0.36 (-0.77, 0.04)	
p-value [3]		0.529		0.045	
					0.344

Abdominal Pain Severity					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	33	58	38	81	
Mean (StdDev)	3.90 (2.563)	4.22 (2.296)	4.06 (2.430)	3.63 (2.236)	
Median	3.75	4.00	4.29	3.08	
Min, Max	0.0, 9.6	0.0, 9.8	0.0, 8.7	0.0, 8.8	

Abdominal Pain Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	33	59	38	78	
Mean (StdDev)	3.05 (2.251)	3.46 (2.038)	3.40 (2.190)	2.93 (2.254)	
Median	2.92	3.29	3.59	2.39	
Min, Max	0.0, 8.9	0.0, 8.0	0.1, 7.5	0.0, 9.4	
C2D1 CFB					
n	33	57	38	78	
LS Mean (StdErr) [2]	-0.88 (0.207)	-0.85 (0.173)	-0.50 (0.202)	-0.54 (0.151)	
95% CI [2]	-1.29, -0.47	-1.20, -0.51	-0.90, -0.10	-0.84, -0.24	
Difference (95% CI) in CFB [2]		0.03 (-0.44, 0.50)		-0.03 (-0.48, 0.41)	
p-value [3]		0.907		0.881	

Abdominal Pain Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	33	58	38	77	
Mean (StdDev)	3.05 (2.285)	3.18 (2.125)	3.06 (2.220)	2.47 (2.176)	
Median	2.82	3.11	3.14	2.14	
Min, Max	0.0, 8.4	0.0, 8.3	0.0, 7.4	0.0, 8.3	
C3D1 CFB					
n	33	56	38	77	
LS Mean (StdErr) [2]	-0.91 (0.289)	-1.19 (0.242)	-0.75 (0.237)	-0.87 (0.178)	
95% CI [2]	-1.48, -0.33	-1.67, -0.70	-1.22, -0.28	-1.23, -0.52	
Difference (95% CI) in CFB [2]		-0.28 (-0.94, 0.38)		-0.13 (-0.65, 0.40)	
p-value [3]		0.404		0.637	

Abdominal Pain Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	31	58	37	77	
Mean (StdDev)	2.89 (2.232)	2.87 (2.218)	3.12 (2.186)	2.26 (2.129)	
Median	2.50	2.48	3.29	2.00	
Min, Max	0.0, 7.9	0.0, 8.4	0.0, 7.3	0.0, 9.1	
C4D1 CFB					
n	31	56	37	77	
LS Mean (StdErr) [2]	-1.16 (0.381)	-1.50 (0.308)	-0.74 (0.257)	-1.11 (0.191)	
95% CI [2]	-1.92, -0.40	-2.12, -0.89	-1.25, -0.23	-1.49, -0.73	
Difference (95% CI) in CFB [2]		-0.34 (-1.19, 0.51)		-0.37 (-0.93, 0.20)	
p-value [3]		0.423		0.203	

Abdominal Pain Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	30	59	37	78	
Mean (StdDev)	3.02 (2.398)	2.74 (2.207)	3.17 (2.078)	2.18 (2.290)	
Median	2.69	2.25	3.00	1.45	
Min, Max	0.0, 8.1	0.0, 8.8	0.0, 6.9	0.0, 9.4	
C5D1 CFB					
n	30	57	37	78	
LS Mean (StdErr) [2]	-1.08 (0.397)	-1.63 (0.310)	-0.60 (0.301)	-1.13 (0.223)	
95% CI [2]	-1.87, -0.29	-2.25, -1.02	-1.20, -0.01	-1.57, -0.68	
Difference (95% CI) in CFB [2]		-0.55 (-1.44, 0.33)		-0.52 (-1.18, 0.14)	
p-value [3]		0.219		0.121	

Abdominal Pain Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	29	58	37	78	
Mean (StdDev)	2.28 (2.031)	2.50 (2.194)	2.85 (2.118)	2.11 (2.241)	
Median	2.07	2.32	2.79	1.42	
Min, Max	0.0, 6.9	0.0, 8.9	0.0, 7.1	0.0, 9.6	
C6D1 CFB					
n	29	56	37	78	
LS Mean (StdErr) [2]	-1.51 (0.405)	-1.80 (0.316)	-0.90 (0.300)	-1.21 (0.221)	
95% CI [2]	-2.32, -0.71	-2.43, -1.17	-1.50, -0.31	-1.65, -0.77	
Difference (95% CI) in CFB [2]		-0.29 (-1.20, 0.63)		-0.31 (-0.96, 0.35)	
p-value [3]		0.534		0.361	

Abdominal Pain Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	30	57	36	76	
Mean (StdDev)	2.62 (2.519)	2.46 (2.121)	2.90 (2.114)	2.20 (2.240)	
Median	2.07	2.17	3.07	1.69	
Min, Max	0.0, 8.3	0.0, 8.6	0.0, 7.1	0.0, 9.4	
C7D1 CFB					
n	30	55	36	76	
LS Mean (StdErr) [2]	-1.29 (0.414)	-1.88 (0.333)	-0.89 (0.282)	-1.12 (0.206)	
95% CI [2]	-2.12, -0.47	-2.54, -1.22	-1.45, -0.33	-1.53, -0.71	
Difference (95% CI) in CFB [2]		-0.59 (-1.52, 0.34)		-0.24 (-0.86, 0.38)	
Hedges'G (95% CI) in CFB		-0.24 (-0.70, 0.20)		-0.13 (-0.54, 0.27)	
p-value [3]		0.213		0.451	
					0.544

Nausea Severity					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	33	58	38	81	
Mean (StdDev)	3.23 (2.529)	3.39 (2.652)	3.48 (2.507)	2.62 (2.434)	
Median	2.71	3.24	3.29	2.29	
Min, Max	0.0, 8.9	0.0, 9.0	0.0, 7.8	0.0, 8.9	

Nausea Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	33	59	38	78	
Mean (StdDev)	2.73 (2.470)	3.10 (2.247)	2.97 (2.301)	2.15 (2.321)	
Median	2.21	3.10	2.71	1.25	
Min, Max	0.0, 8.3	0.0, 8.2	0.0, 7.7	0.0, 8.8	
C2D1 CFB					
n	33	57	38	78	
LS Mean (StdErr) [2]	-0.43 (0.250)	-0.31 (0.209)	-0.41 (0.206)	-0.34 (0.154)	
95% CI [2]	-0.93, 0.07	-0.73, 0.11	-0.81, 0.00	-0.64, -0.03	
Difference (95% CI) in CFB [2]		0.12 (-0.45, 0.69)		0.07 (-0.38, 0.52)	
p-value [3]		0.674		0.756	

Nausea Severity					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	33	58	38	77	
Mean (StdDev)	2.59 (2.427)	2.82 (2.207)	2.47 (2.215)	1.90 (2.206)	
Median	2.09	2.50	1.85	1.14	
Min, Max	0.0, 7.7	0.0, 7.9	0.0, 7.4	0.0, 8.9	
C3D1 CFB					
n	33	56	38	77	
LS Mean (StdErr) [2]	-0.56 (0.317)	-0.60 (0.266)	-0.96 (0.231)	-0.61 (0.173)	
95% CI [2]	-1.19, 0.07	-1.12, -0.07	-1.41, -0.50	-0.95, -0.27	
Difference (95% CI) in CFB [2]		-0.03 (-0.76, 0.69)		0.35 (-0.16, 0.86)	
p-value [3]		0.926		0.180	

Nausea Severity

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	31	58	37	77	
Mean (StdDev)	2.58 (2.275)	2.36 (2.220)	2.60 (2.247)	1.74 (2.185)	
Median	1.86	1.79	2.79	0.79	
Min, Max	0.0, 7.4	0.0, 8.4	0.0, 7.0	0.0, 9.2	
C4D1 CFB					
n	31	56	37	77	
LS Mean (StdErr) [2]	-0.73 (0.363)	-1.14 (0.294)	-0.93 (0.261)	-0.82 (0.194)	
95% CI [2]	-1.45, -0.01	-1.73, -0.56	-1.44, -0.41	-1.20, -0.43	
Difference (95% CI) in CFB [2]		-0.42 (-1.22, 0.39)		0.11 (-0.47, 0.68)	
p-value [3]		0.310		0.713	

Nausea Severity

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	30	59	37	78	
Mean (StdDev)	2.77 (2.522)	2.24 (2.252)	2.54 (1.991)	1.80 (2.177)	
Median	2.83	1.62	2.36	1.00	
Min, Max	0.0, 8.5	0.0, 8.9	0.0, 6.6	0.0, 8.4	
C5D1 CFB					
n	30	57	37	78	
LS Mean (StdErr) [2]	-0.63 (0.372)	-1.28 (0.290)	-0.90 (0.301)	-0.69 (0.223)	
95% CI [2]	-1.37, 0.10	-1.85, -0.70	-1.50, -0.30	-1.13, -0.25	
Difference (95% CI) in CFB [2]		-0.64 (-1.47, 0.19)		0.21 (-0.45, 0.87)	
p-value [3]		0.128		0.531	

Nausea Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	29	58	37	78	
Mean (StdDev)	2.32 (2.348)	1.95 (2.221)	2.30 (1.957)	1.66 (2.077)	
Median	1.71	1.46	2.21	1.04	
Min, Max	0.0, 7.9	0.0, 8.9	0.0, 6.7	0.0, 9.9	
C6D1 CFB					
n	29	56	37	78	
LS Mean (StdErr) [2]	-0.97 (0.397)	-1.49 (0.309)	-1.20 (0.276)	-0.91 (0.203)	
95% CI [2]	-1.76, -0.18	-2.10, -0.87	-1.75, -0.65	-1.31, -0.51	
Difference (95% CI) in CFB [2]		-0.52 (-1.41, 0.38)		0.29 (-0.31, 0.90)	
p-value [3]		0.253		0.342	

Nausea Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	30	57	36	76	
Mean (StdDev)	2.41 (2.442)	2.00 (2.141)	2.41 (2.166)	1.70 (2.133)	
Median	1.93	1.45	1.54	0.91	
Min, Max	0.0, 7.7	0.0, 8.3	0.0, 6.3	0.0, 9.5	
C7D1 CFB					
n	30	55	36	76	
LS Mean (StdErr) [2]	-1.01 (0.414)	-1.46 (0.332)	-0.96 (0.313)	-0.81 (0.229)	
95% CI [2]	-1.84, -0.19	-2.12, -0.80	-1.59, -0.34	-1.27, -0.36	
Difference (95% CI) in CFB [2]		-0.44 (-1.37, 0.49)		0.15 (-0.54, 0.84)	
Hedges'G (95% CI) in CFB		-0.18 (-0.64, 0.26)		0.08 (-0.32, 0.48)	
p-value [3]		0.346		0.664	
					0.311

Spots Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	33	58	38	81	
Mean (StdDev)	6.29 (3.142)	5.25 (3.316)	5.32 (3.100)	5.33 (2.839)	
Median	7.00	4.92	5.57	5.71	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	

Spots Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	33	59	38	78	
Mean (StdDev)	6.05 (2.963)	4.67 (3.085)	4.82 (2.858)	4.27 (2.545)	
Median	6.62	5.00	5.18	4.21	
Min, Max	0.0, 10.0	0.0, 9.9	0.0, 10.0	0.0, 10.0	
C2D1 CFB					
n	33	57	38	78	
LS Mean (StdErr) [2]	-0.19 (0.197)	-0.58 (0.165)	-0.40 (0.242)	-1.00 (0.181)	
95% CI [2]	-0.58, 0.20	-0.91, -0.25	-0.88, 0.08	-1.36, -0.64	
Difference (95% CI) in CFB [2]		-0.39 (-0.83, 0.06)		-0.60 (-1.13, -0.06)	
p-value [3]		0.090		0.028	

Spots Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	33	58	38	77	
Mean (StdDev)	6.19 (2.886)	4.25 (3.013)	4.62 (2.911)	3.89 (2.331)	
Median	6.07	3.82	4.27	4.00	
Min, Max	0.0, 10.0	0.0, 9.8	0.0, 10.0	0.0, 9.0	
C3D1 CFB					
n	33	56	38	77	
LS Mean (StdErr) [2]	0.06 (0.217)	-0.91 (0.182)	-0.54 (0.310)	-1.34 (0.232)	
95% CI [2]	-0.37, 0.49	-1.27, -0.55	-1.15, 0.08	-1.80, -0.88	
Difference (95% CI) in CFB [2]		-0.97 (-1.47, -0.48)		-0.80 (-1.48, -0.11)	
p-value [3]		<0.001		0.023	

Spots Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	31	58	37	77	
Mean (StdDev)	6.19 (3.056)	4.04 (2.915)	4.46 (2.774)	3.68 (2.403)	
Median	6.75	3.77	4.07	3.54	
Min, Max	0.0, 10.0	0.0, 9.3	0.0, 10.0	0.0, 9.4	
C4D1 CFB					
n	31	56	37	77	
LS Mean (StdErr) [2]	0.10 (0.237)	-1.00 (0.192)	-0.44 (0.321)	-1.46 (0.239)	
95% CI [2]	-0.38, 0.57	-1.38, -0.61	-1.08, 0.20	-1.93, -0.98	
Difference (95% CI) in CFB [2]		-1.09 (-1.62, -0.56)		-1.02 (-1.73, -0.31)	
p-value [3]		<0.0001		0.005	

Spots Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	30	59	37	78	
Mean (StdDev)	6.17 (3.149)	3.71 (2.832)	4.28 (2.688)	3.58 (2.397)	
Median	6.61	3.00	4.00	3.18	
Min, Max	0.0, 10.0	0.0, 9.3	0.0, 10.0	0.0, 9.9	
C5D1 CFB					
n	30	57	37	78	
LS Mean (StdErr) [2]	0.00 (0.285)	-1.42 (0.223)	-0.67 (0.335)	-1.55 (0.248)	
95% CI [2]	-0.56, 0.57	-1.86, -0.97	-1.33, -0.00	-2.04, -1.06	
Difference (95% CI) in CFB [2]		-1.42 (-2.06, -0.78)		-0.89 (-1.62, -0.15)	
p-value [3]		<0.0001		0.019	

Spots Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	29	58	37	78	
Mean (StdDev)	6.20 (2.995)	3.50 (2.659)	4.40 (2.881)	3.47 (2.550)	
Median	5.64	3.24	4.21	3.07	
Min, Max	0.0, 10.0	0.0, 9.1	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	29	56	37	78	
LS Mean (StdErr) [2]	-0.01 (0.326)	-1.52 (0.254)	-0.45 (0.391)	-1.58 (0.288)	
95% CI [2]	-0.66, 0.64	-2.03, -1.01	-1.22, 0.33	-2.15, -1.01	
Difference (95% CI) in CFB [2]		-1.51 (-2.24, -0.78)		-1.13 (-1.99, -0.27)	
p-value [3]		<0.0001		0.011	

Spots Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	30	57	36	76	
Mean (StdDev)	6.18 (3.044)	3.37 (2.744)	4.44 (2.717)	3.55 (2.616)	
Median	5.93	3.08	4.04	3.16	
Min, Max	0.0, 10.0	0.0, 9.0	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	30	55	36	76	
LS Mean (StdErr) [2]	-0.11 (0.323)	-1.73 (0.259)	-0.52 (0.402)	-1.51 (0.294)	
95% CI [2]	-0.75, 0.54	-2.25, -1.22	-1.32, 0.27	-2.09, -0.93	
Difference (95% CI) in CFB [2]		-1.63 (-2.35, -0.90)		-0.99 (-1.87, -0.10)	
Hedges'G (95% CI) in CFB		-0.86 (-1.36, -0.41)		-0.39 (-0.80, 0.01)	
p-value [3]		<0.0001		0.029	
					0.270

Itching Severity					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	33	58	38	81	
Mean (StdDev)	6.07 (2.754)	5.14 (2.756)	5.40 (2.821)	5.13 (2.854)	
Median	6.71	4.99	5.77	5.14	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	

Itching Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	33	59	38	78	
Mean (StdDev)	5.36 (2.936)	4.30 (2.475)	4.83 (2.700)	3.94 (2.513)	
Median	5.79	4.21	5.14	4.11	
Min, Max	0.0, 9.8	0.0, 9.9	0.0, 10.0	0.0, 9.6	
C2D1 CFB					
n	33	57	38	78	
LS Mean (StdErr) [2]	-0.92 (0.286)	-1.15 (0.239)	-0.43 (0.289)	-1.08 (0.217)	
95% CI [2]	-1.49, -0.35	-1.62, -0.67	-1.01, 0.14	-1.51, -0.65	
Difference (95% CI) in CFB [2]		-0.23 (-0.88, 0.42)		-0.64 (-1.28, -0.01)	
p-value [3]		0.480		0.048	

Itching Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	33	58	38	77	
Mean (StdDev)	5.19 (3.024)	3.66 (2.303)	4.43 (2.613)	3.36 (2.625)	
Median	5.58	3.33	4.38	3.00	
Min, Max	0.0, 9.9	0.0, 8.2	0.0, 10.0	0.0, 9.7	
C3D1 CFB					
n	33	56	38	77	
LS Mean (StdErr) [2]	-0.91 (0.312)	-1.55 (0.261)	-0.81 (0.383)	-1.64 (0.287)	
95% CI [2]	-1.53, -0.29	-2.07, -1.03	-1.56, -0.05	-2.21, -1.07	
Difference (95% CI) in CFB [2]		-0.64 (-1.35, 0.07)		-0.83 (-1.68, 0.01)	
p-value [3]		0.075		0.053	

Itching Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	31	58	37	77	
Mean (StdDev)	4.97 (3.248)	3.41 (2.385)	4.43 (2.536)	3.17 (2.725)	
Median	5.50	3.31	4.86	2.43	
Min, Max	0.0, 9.8	0.0, 9.1	0.0, 10.0	0.0, 10.0	
C4D1 CFB					
n	31	56	37	77	
LS Mean (StdErr) [2]	-1.39 (0.396)	-1.95 (0.320)	-0.72 (0.427)	-1.81 (0.317)	
95% CI [2]	-2.17, -0.60	-2.59, -1.32	-1.56, 0.13	-2.44, -1.18	
Difference (95% CI) in CFB [2]		-0.57 (-1.45, 0.31)		-1.09 (-2.03, -0.15)	
p-value [3]		0.204		0.024	

Itching Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	30	59	37	78	
Mean (StdDev)	5.25 (3.161)	3.08 (2.201)	4.37 (2.381)	3.03 (2.758)	
Median	5.75	2.93	4.29	2.50	
Min, Max	0.0, 10.0	0.0, 8.3	0.0, 10.0	0.0, 10.0	
C5D1 CFB					
n	30	57	37	78	
LS Mean (StdErr) [2]	-1.16 (0.407)	-2.28 (0.318)	-0.68 (0.443)	-1.82 (0.328)	
95% CI [2]	-1.97, -0.35	-2.91, -1.65	-1.56, 0.20	-2.47, -1.17	
Difference (95% CI) in CFB [2]		-1.12 (-2.03, -0.21)		-1.14 (-2.12, -0.17)	
p-value [3]		0.016		0.022	

Itching Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	29	58	37	78	
Mean (StdDev)	4.97 (3.067)	3.14 (2.303)	4.51 (2.503)	2.91 (2.690)	
Median	4.75	3.00	4.77	2.12	
Min, Max	0.0, 10.0	0.0, 8.2	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	29	56	37	78	
LS Mean (StdErr) [2]	-1.41 (0.431)	-2.20 (0.335)	-0.57 (0.449)	-2.01 (0.331)	
95% CI [2]	-2.27, -0.56	-2.86, -1.53	-1.46, 0.32	-2.66, -1.35	
Difference (95% CI) in CFB [2]		-0.78 (-1.75, 0.19)		-1.44 (-2.43, -0.45)	
p-value [3]		0.113		0.005	

Itching Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	30	57	36	76	
Mean (StdDev)	5.04 (3.186)	2.96 (2.232)	4.66 (2.130)	2.99 (2.717)	
Median	5.22	2.91	4.54	2.23	
Min, Max	0.0, 10.0	0.0, 9.0	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	30	55	36	76	
LS Mean (StdErr) [2]	-1.41 (0.457)	-2.39 (0.367)	-0.46 (0.456)	-1.90 (0.333)	
95% CI [2]	-2.32, -0.50	-3.12, -1.66	-1.36, 0.44	-2.56, -1.24	
Difference (95% CI) in CFB [2]		-0.98 (-2.00, 0.05)		-1.44 (-2.44, -0.43)	
Hedges'G (95% CI) in CFB		-0.37 (-0.83, 0.08)		-0.50 (-0.92, -0.10)	
p-value [3]		0.061		0.005	
					0.547

Flushing Severity					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	33	58	38	81	
Mean (StdDev)	6.25 (2.337)	5.32 (2.336)	5.25 (2.857)	4.89 (2.655)	
Median	6.07	5.04	5.29	5.29	
Min, Max	1.0, 10.0	0.0, 10.0	0.0, 10.0	0.0, 9.9	

Flushing Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	33	59	38	78	
Mean (StdDev)	5.67 (2.310)	4.58 (2.204)	4.74 (2.996)	4.23 (2.750)	
Median	5.73	4.43	4.21	4.18	
Min, Max	1.2, 10.0	0.0, 8.6	0.0, 10.0	0.0, 10.0	
C2D1 CFB					
n	33	57	38	78	
LS Mean (StdErr) [2]	-0.63 (0.230)	-0.82 (0.193)	-0.48 (0.294)	-0.66 (0.220)	
95% CI [2]	-1.09, -0.17	-1.20, -0.43	-1.07, 0.10	-1.09, -0.22	
Difference (95% CI) in CFB [2]		-0.18 (-0.71, 0.34)		-0.17 (-0.82, 0.47)	
p-value [3]		0.486		0.597	

Flushing Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	33	58	38	77	
Mean (StdDev)	5.42 (2.759)	4.08 (2.306)	4.59 (2.941)	3.80 (2.627)	
Median	5.57	3.90	4.18	3.79	
Min, Max	0.0, 9.8	0.0, 9.1	0.0, 10.0	0.0, 10.0	
C3D1 CFB					
n	33	56	38	77	
LS Mean (StdErr) [2]	-0.82 (0.305)	-1.28 (0.256)	-0.52 (0.337)	-0.99 (0.253)	
95% CI [2]	-1.42, -0.21	-1.79, -0.77	-1.19, 0.15	-1.49, -0.49	
Difference (95% CI) in CFB [2]		-0.46 (-1.16, 0.23)		-0.47 (-1.22, 0.27)	
p-value [3]		0.187		0.212	

Flushing Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	31	58	37	77	
Mean (StdDev)	5.26 (2.793)	3.90 (2.348)	4.74 (2.980)	3.57 (2.647)	
Median	5.57	3.68	4.21	3.46	
Min, Max	0.1, 9.8	0.0, 9.3	0.0, 10.0	0.0, 10.0	
C4D1 CFB					
n	31	56	37	77	
LS Mean (StdErr) [2]	-1.12 (0.362)	-1.60 (0.293)	-0.37 (0.377)	-1.20 (0.280)	
95% CI [2]	-1.84, -0.40	-2.18, -1.02	-1.12, 0.38	-1.75, -0.64	
Difference (95% CI) in CFB [2]		-0.48 (-1.29, 0.33)		-0.83 (-1.66, 0.00)	
p-value [3]		0.243		0.051	

Flushing Severity					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	30	59	37	78	
Mean (StdDev)	5.23 (2.824)	3.73 (2.198)	4.73 (3.024)	3.48 (2.726)	
Median	5.45	3.64	4.36	3.17	
Min, Max	0.2, 10.0	0.0, 8.8	0.0, 10.0	0.0, 9.8	
C5D1 CFB					
n	30	57	37	78	
LS Mean (StdErr) [2]	-1.11 (0.372)	-1.75 (0.291)	-0.50 (0.438)	-1.38 (0.324)	
95% CI [2]	-1.85, -0.37	-2.32, -1.17	-1.36, 0.37	-2.03, -0.74	
Difference (95% CI) in CFB [2]		-0.63 (-1.46, 0.20)		-0.89 (-1.85, 0.07)	
p-value [3]		0.134		0.070	

Flushing Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	29	58	37	78	
Mean (StdDev)	5.23 (2.726)	3.62 (2.253)	4.53 (3.090)	3.29 (2.715)	
Median	5.42	3.43	3.93	2.65	
Min, Max	0.1, 10.0	0.0, 9.1	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	29	56	37	78	
LS Mean (StdErr) [2]	-1.19 (0.414)	-1.84 (0.322)	-0.66 (0.433)	-1.54 (0.319)	
95% CI [2]	-2.01, -0.37	-2.48, -1.20	-1.52, 0.19	-2.17, -0.90	
Difference (95% CI) in CFB [2]		-0.65 (-1.58, 0.28)		-0.87 (-1.82, 0.08)	
p-value [3]		0.170		0.072	

Flushing Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	30	57	36	76	
Mean (StdDev)	5.16 (2.864)	3.21 (2.328)	4.71 (2.913)	3.30 (2.611)	
Median	5.57	3.17	4.07	2.57	
Min, Max	0.4, 10.0	0.0, 9.5	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	30	55	36	76	
LS Mean (StdErr) [2]	-1.29 (0.451)	-2.21 (0.362)	-0.44 (0.427)	-1.35 (0.313)	
95% CI [2]	-2.19, -0.40	-2.93, -1.49	-1.29, 0.40	-1.97, -0.73	
Difference (95% CI) in CFB [2]		-0.91 (-1.93, 0.10)		-0.91 (-1.85, 0.03)	
Hedges'G (95% CI) in CFB		-0.35 (-0.81, 0.10)		-0.34 (-0.75, 0.06)	
p-value [3]		0.077		0.058	
					0.999

Fatigue Severity					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	33	58	38	81	
Mean (StdDev)	6.56 (2.188)	6.52 (2.099)	6.85 (1.865)	6.75 (2.142)	
Median	6.62	6.50	6.75	7.00	
Min, Max	0.0, 10.0	0.1, 10.0	3.3, 10.0	1.5, 10.0	

Fatigue Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	33	59	38	78	
Mean (StdDev)	5.99 (2.129)	5.96 (2.302)	6.56 (1.824)	5.97 (2.333)	
Median	5.93	6.14	6.61	6.11	
Min, Max	2.3, 10.0	0.1, 10.0	2.8, 9.9	0.7, 10.0	
C2D1 CFB					
n	33	57	38	78	
LS Mean (StdErr) [2]	-0.70 (0.213)	-0.74 (0.178)	-0.25 (0.226)	-0.75 (0.169)	
95% CI [2]	-1.13, -0.28	-1.09, -0.38	-0.69, 0.20	-1.09, -0.42	
Difference (95% CI) in CFB [2]		-0.03 (-0.52, 0.45)		-0.51 (-1.00, -0.01)	
p-value [3]		0.892		0.047	

Fatigue Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	33	58	38	77	
Mean (StdDev)	5.78 (2.519)	5.57 (2.208)	6.04 (2.178)	5.54 (2.466)	
Median	5.64	5.78	6.04	5.57	
Min, Max	0.3, 10.0	0.7, 10.0	1.6, 9.9	0.2, 10.0	
C3D1 CFB					
n	33	56	38	77	
LS Mean (StdErr) [2]	-0.83 (0.283)	-1.00 (0.237)	-0.83 (0.287)	-1.22 (0.215)	
95% CI [2]	-1.39, -0.27	-1.47, -0.53	-1.40, -0.26	-1.65, -0.79	
Difference (95% CI) in CFB [2]		-0.17 (-0.81, 0.48)		-0.39 (-1.02, 0.25)	
p-value [3]		0.606		0.229	

Fatigue Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	31	58	37	77	
Mean (StdDev)	5.52 (2.720)	5.18 (2.396)	5.82 (2.207)	5.35 (2.565)	
Median	5.31	5.12	6.07	5.38	
Min, Max	0.2, 10.0	0.0, 10.0	1.5, 9.9	0.0, 10.0	
C4D1 CFB					
n	31	56	37	77	
LS Mean (StdErr) [2]	-1.24 (0.345)	-1.58 (0.280)	-0.97 (0.348)	-1.37 (0.259)	
95% CI [2]	-1.93, -0.56	-2.13, -1.02	-1.66, -0.28	-1.88, -0.85	
Difference (95% CI) in CFB [2]		-0.33 (-1.10, 0.44)		-0.40 (-1.17, 0.37)	
p-value [3]		0.393		0.306	

Fatigue Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	30	59	37	78	
Mean (StdDev)	5.41 (2.828)	5.11 (2.217)	5.68 (2.101)	5.31 (2.658)	
Median	5.38	5.30	5.64	5.39	
Min, Max	0.6, 10.0	0.0, 10.0	1.5, 9.9	0.0, 10.0	
C5D1 CFB					
n	30	57	37	78	
LS Mean (StdErr) [2]	-1.33 (0.327)	-1.59 (0.256)	-0.97 (0.380)	-1.28 (0.281)	
95% CI [2]	-1.98, -0.68	-2.10, -1.08	-1.72, -0.22	-1.84, -0.73	
Difference (95% CI) in CFB [2]		-0.27 (-1.00, 0.47)		-0.31 (-1.15, 0.52)	
p-value [3]		0.473		0.459	

Fatigue Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	29	58	37	78	
Mean (StdDev)	5.52 (2.847)	4.99 (2.448)	5.68 (2.107)	5.03 (2.801)	
Median	5.07	5.12	6.00	5.00	
Min, Max	0.4, 10.0	0.0, 10.0	1.2, 10.0	0.0, 10.0	
C6D1 CFB					
n	29	56	37	78	
LS Mean (StdErr) [2]	-1.12 (0.379)	-1.67 (0.295)	-0.98 (0.390)	-1.54 (0.288)	
95% CI [2]	-1.87, -0.37	-2.25, -1.08	-1.75, -0.20	-2.11, -0.97	
Difference (95% CI) in CFB [2]		-0.55 (-1.40, 0.31)		-0.56 (-1.42, 0.30)	
p-value [3]		0.206		0.199	

Fatigue Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	30	57	36	76	
Mean (StdDev)	5.40 (2.958)	4.87 (2.402)	5.73 (2.108)	4.90 (2.723)	
Median	5.55	5.15	5.50	4.87	
Min, Max	0.2, 10.0	0.0, 10.0	1.8, 10.0	0.0, 10.0	
C7D1 CFB					
n	30	55	36	76	
LS Mean (StdErr) [2]	-1.34 (0.391)	-1.87 (0.314)	-0.87 (0.393)	-1.58 (0.288)	
95% CI [2]	-2.12, -0.56	-2.49, -1.24	-1.65, -0.09	-2.15, -1.01	
Difference (95% CI) in CFB [2]		-0.53 (-1.41, 0.35)		-0.72 (-1.58, 0.15)	
Hedges'G (95% CI) in CFB		-0.23 (-0.69, 0.22)		-0.29 (-0.70, 0.11)	
p-value [3]		0.234		0.104	
					0.715

Dizziness Severity					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	33	58	38	81	
Mean (StdDev)	3.78 (2.935)	3.29 (2.680)	3.39 (2.629)	3.89 (2.988)	
Median	3.00	3.34	2.39	3.71	
Min, Max	0.0, 9.3	0.0, 8.9	0.0, 8.4	0.0, 10.0	

Dizziness Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	33	59	38	78	
Mean (StdDev)	3.02 (2.746)	2.92 (2.410)	3.21 (2.586)	3.23 (2.849)	
Median	2.46	2.58	2.93	2.96	
Min, Max	0.0, 8.4	0.0, 8.1	0.0, 8.7	0.0, 10.0	
C2D1 CFB					
n	33	57	38	78	
LS Mean (StdErr) [2]	-0.79 (0.217)	-0.50 (0.181)	-0.08 (0.262)	-0.57 (0.196)	
95% CI [2]	-1.22, -0.36	-0.87, -0.14	-0.59, 0.44	-0.96, -0.19	
Difference (95% CI) in CFB [2]		0.28 (-0.21, 0.78)		-0.50 (-1.08, 0.08)	
p-value [3]		0.256		0.090	

Dizziness Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	33	58	38	77	
Mean (StdDev)	2.94 (2.653)	2.74 (2.400)	2.61 (2.503)	2.78 (2.861)	
Median	2.54	2.23	1.88	2.00	
Min, Max	0.0, 8.1	0.0, 8.1	0.0, 7.6	0.0, 10.0	
C3D1 CFB					
n	33	56	38	77	
LS Mean (StdErr) [2]	-0.80 (0.280)	-0.63 (0.235)	-0.64 (0.294)	-1.00 (0.221)	
95% CI [2]	-1.36, -0.24	-1.10, -0.16	-1.22, -0.06	-1.43, -0.56	
Difference (95% CI) in CFB [2]		0.17 (-0.46, 0.81)		-0.36 (-1.01, 0.29)	
p-value [3]		0.590		0.279	

Dizziness Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	31	58	37	77	
Mean (StdDev)	2.98 (2.693)	2.54 (2.471)	2.84 (2.635)	2.77 (2.882)	
Median	2.21	1.84	2.50	1.93	
Min, Max	0.0, 8.1	0.0, 8.1	0.0, 9.9	0.0, 10.0	
C4D1 CFB					
n	31	56	37	77	
LS Mean (StdErr) [2]	-0.91 (0.365)	-0.94 (0.295)	-0.42 (0.333)	-1.03 (0.247)	
95% CI [2]	-1.64, -0.19	-1.53, -0.35	-1.08, 0.24	-1.52, -0.54	
Difference (95% CI) in CFB [2]		-0.03 (-0.84, 0.78)		-0.61 (-1.35, 0.12)	
p-value [3]		0.944		0.099	

Dizziness Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	30	59	37	78	
Mean (StdDev)	3.06 (2.753)	2.40 (2.479)	2.82 (2.493)	2.65 (2.746)	
Median	2.32	1.62	2.31	2.00	
Min, Max	0.0, 8.0	0.0, 8.0	0.0, 9.6	0.0, 10.0	
C5D1 CFB					
n	30	57	37	78	
LS Mean (StdErr) [2]	-0.83 (0.336)	-1.01 (0.263)	-0.33 (0.344)	-1.04 (0.254)	
95% CI [2]	-1.50, -0.16	-1.53, -0.49	-1.01, 0.35	-1.54, -0.54	
Difference (95% CI) in CFB [2]		-0.18 (-0.93, 0.57)		-0.71 (-1.47, 0.04)	
p-value [3]		0.641		0.064	

Dizziness Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	29	58	37	78	
Mean (StdDev)	2.82 (2.729)	2.21 (2.263)	2.60 (2.515)	2.38 (2.701)	
Median	1.71	1.65	1.71	1.59	
Min, Max	0.0, 8.3	0.0, 8.2	0.0, 8.6	0.0, 10.0	
C6D1 CFB					
n	29	56	37	78	
LS Mean (StdErr) [2]	-1.06 (0.380)	-1.12 (0.296)	-0.63 (0.356)	-1.36 (0.263)	
95% CI [2]	-1.81, -0.30	-1.71, -0.53	-1.33, 0.08	-1.88, -0.84	
Difference (95% CI) in CFB [2]		-0.06 (-0.92, 0.79)		-0.73 (-1.52, 0.05)	
p-value [3]		0.883		0.067	

Dizziness Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	30	57	36	76	
Mean (StdDev)	2.88 (2.848)	2.15 (2.299)	2.59 (2.485)	2.45 (2.720)	
Median	1.82	1.36	1.96	1.82	
Min, Max	0.0, 8.8	0.0, 8.3	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	30	55	36	76	
LS Mean (StdErr) [2]	-1.19 (0.402)	-1.19 (0.323)	-0.51 (0.364)	-1.26 (0.266)	
95% CI [2]	-1.99, -0.39	-1.84, -0.55	-1.24, 0.21	-1.79, -0.73	
Difference (95% CI) in CFB [2]		-0.01 (-0.91, 0.90)		-0.74 (-1.55, 0.06)	
Hedges'G (95% CI) in CFB		-0.00 (-0.45, 0.45)		-0.32 (-0.73, 0.07)	
p-value [3]		0.988		0.068	
					0.221

Brain Fog Severity					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	33	58	38	81	
Mean (StdDev)	5.63 (2.685)	5.54 (2.226)	4.51 (2.723)	5.26 (2.693)	
Median	5.75	5.63	4.86	5.21	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 9.4	0.0, 10.0	

Brain Fog Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	33	59	38	78	
Mean (StdDev)	4.77 (2.813)	5.05 (2.373)	4.32 (2.542)	4.49 (2.886)	
Median	4.57	5.21	4.11	4.25	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 9.5	0.0, 10.0	
C2D1 CFB					
n	33	57	38	78	
LS Mean (StdErr) [2]	-1.04 (0.203)	-0.76 (0.170)	0.01 (0.205)	-0.57 (0.153)	
95% CI [2]	-1.45, -0.64	-1.10, -0.42	-0.39, 0.42	-0.88, -0.27	
Difference (95% CI) in CFB [2]		0.29 (-0.18, 0.75)		-0.59 (-1.04, -0.14)	
p-value [3]		0.221		0.011	

Brain Fog Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	33	58	38	77	
Mean (StdDev)	4.79 (2.818)	4.56 (2.496)	3.89 (2.608)	4.29 (2.891)	
Median	4.45	4.63	3.64	3.93	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 9.2	0.0, 10.0	
C3D1 CFB					
n	33	56	38	77	
LS Mean (StdErr) [2]	-0.99 (0.260)	-1.19 (0.218)	-0.46 (0.245)	-0.86 (0.183)	
95% CI [2]	-1.51, -0.48	-1.62, -0.76	-0.95, 0.03	-1.22, -0.50	
Difference (95% CI) in CFB [2]		-0.20 (-0.79, 0.40)		-0.40 (-0.94, 0.14)	
p-value [3]		0.513		0.146	

Brain Fog Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	31	58	37	77	
Mean (StdDev)	4.33 (2.964)	4.22 (2.578)	3.90 (2.662)	4.15 (3.032)	
Median	4.29	4.15	3.86	3.50	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 9.9	0.0, 10.0	
C4D1 CFB					
n	31	56	37	77	
LS Mean (StdErr) [2]	-1.52 (0.341)	-1.68 (0.276)	-0.47 (0.284)	-0.91 (0.211)	
95% CI [2]	-2.20, -0.84	-2.23, -1.13	-1.03, 0.09	-1.33, -0.49	
Difference (95% CI) in CFB [2]		-0.16 (-0.92, 0.60)		-0.44 (-1.07, 0.18)	
p-value [3]		0.679		0.162	

Brain Fog Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	30	59	37	78	
Mean (StdDev)	4.02 (3.035)	4.13 (2.504)	3.83 (2.609)	4.19 (3.104)	
Median	3.62	4.00	3.50	4.50	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 9.9	0.0, 10.0	
C5D1 CFB					
n	30	57	37	78	
LS Mean (StdErr) [2]	-1.73 (0.366)	-1.65 (0.286)	-0.43 (0.310)	-0.77 (0.229)	
95% CI [2]	-2.46, -1.00	-2.22, -1.08	-1.04, 0.19	-1.22, -0.31	
Difference (95% CI) in CFB [2]		0.09 (-0.73, 0.90)		-0.34 (-1.02, 0.34)	
p-value [3]		0.836		0.325	

Brain Fog Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	29	58	37	78	
Mean (StdDev)	4.17 (3.054)	3.99 (2.571)	3.81 (2.537)	4.00 (3.113)	
Median	3.92	3.89	3.57	3.04	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 9.6	0.0, 10.0	
C6D1 CFB					
n	29	56	37	78	
LS Mean (StdErr) [2]	-1.48 (0.356)	-1.78 (0.277)	-0.46 (0.309)	-0.96 (0.228)	
95% CI [2]	-2.19, -0.77	-2.33, -1.22	-1.07, 0.15	-1.41, -0.51	
Difference (95% CI) in CFB [2]		-0.29 (-1.09, 0.51)		-0.51 (-1.19, 0.17)	
p-value [3]		0.468		0.143	

Brain Fog Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	30	57	36	76	
Mean (StdDev)	4.35 (3.136)	3.87 (2.683)	3.71 (2.612)	3.98 (3.107)	
Median	4.00	3.93	3.29	3.55	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	30	55	36	76	
LS Mean (StdErr) [2]	-1.45 (0.379)	-1.93 (0.304)	-0.50 (0.323)	-0.97 (0.236)	
95% CI [2]	-2.20, -0.69	-2.54, -1.33	-1.14, 0.14	-1.44, -0.50	
Difference (95% CI) in CFB [2]		-0.49 (-1.34, 0.37)		-0.47 (-1.18, 0.24)	
Hedges'G (95% CI) in CFB		-0.22 (-0.68, 0.23)		-0.23 (-0.64, 0.17)	
p-value [3]		0.260		0.193	
					0.979

Headache Severity					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	33	58	38	81	
Mean (StdDev)	4.17 (2.889)	4.02 (2.202)	4.04 (2.582)	4.02 (2.795)	
Median	4.93	3.96	4.07	3.71	
Min, Max	0.0, 9.9	0.0, 8.6	0.4, 8.9	0.0, 9.9	

Headache Severity					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	33	59	38	78	
Mean (StdDev)	3.83 (2.699)	3.52 (2.150)	3.73 (2.534)	3.43 (2.641)	
Median	3.50	3.54	3.75	3.04	
Min, Max	0.0, 9.1	0.1, 8.4	0.0, 8.5	0.0, 10.0	
C2D1 CFB					
n	33	57	38	78	
LS Mean (StdErr) [2]	-0.49 (0.220)	-0.71 (0.184)	-0.18 (0.229)	-0.47 (0.172)	
95% CI [2]	-0.93, -0.05	-1.08, -0.35	-0.64, 0.27	-0.81, -0.13	
Difference (95% CI) in CFB [2]		-0.22 (-0.72, 0.28)		-0.29 (-0.79, 0.22)	
p-value [3]		0.379		0.266	

Headache Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	33	58	38	77	
Mean (StdDev)	3.52 (2.673)	3.21 (2.141)	3.32 (2.503)	3.10 (2.591)	
Median	2.50	3.04	3.18	2.62	
Min, Max	0.0, 9.1	0.0, 8.2	0.0, 8.0	0.0, 10.0	
C3D1 CFB					
n	33	56	38	77	
LS Mean (StdErr) [2]	-0.79 (0.301)	-1.02 (0.253)	-0.53 (0.284)	-0.73 (0.213)	
95% CI [2]	-1.39, -0.19	-1.52, -0.52	-1.10, 0.03	-1.15, -0.31	
Difference (95% CI) in CFB [2]		-0.23 (-0.92, 0.45)		-0.20 (-0.82, 0.43)	
p-value [3]		0.503		0.536	

Headache Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	31	58	37	77	
Mean (StdDev)	3.24 (2.442)	2.92 (2.145)	3.66 (2.544)	3.06 (2.551)	
Median	2.79	2.80	3.71	2.67	
Min, Max	0.0, 8.1	0.0, 7.5	0.0, 8.4	0.0, 9.9	
C4D1 CFB					
n	31	56	37	77	
LS Mean (StdErr) [2]	-1.10 (0.348)	-1.31 (0.282)	-0.37 (0.306)	-0.92 (0.228)	
95% CI [2]	-1.79, -0.40	-1.87, -0.75	-0.98, 0.23	-1.37, -0.47	
Difference (95% CI) in CFB [2]		-0.22 (-0.99, 0.56)		-0.54 (-1.22, 0.13)	
p-value [3]		0.583		0.113	

Headache Severity					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	30	59	37	78	
Mean (StdDev)	3.50 (2.608)	2.83 (2.099)	3.35 (2.408)	2.95 (2.568)	
Median	2.60	2.38	3.50	2.54	
Min, Max	0.0, 9.1	0.0, 8.5	0.0, 8.1	0.0, 10.0	
C5D1 CFB					
n	30	57	37	78	
LS Mean (StdErr) [2]	-0.98 (0.303)	-1.43 (0.237)	-0.65 (0.339)	-1.02 (0.251)	
95% CI [2]	-1.59, -0.38	-1.90, -0.96	-1.32, 0.02	-1.52, -0.53	
Difference (95% CI) in CFB [2]		-0.45 (-1.12, 0.23)		-0.38 (-1.12, 0.37)	
p-value [3]		0.193		0.318	

Headache Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	29	58	37	78	
Mean (StdDev)	2.95 (2.510)	2.61 (2.022)	3.27 (2.487)	2.73 (2.667)	
Median	2.62	2.15	2.79	1.85	
Min, Max	0.0, 8.9	0.0, 8.0	0.0, 8.3	0.0, 10.0	
C6D1 CFB					
n	29	56	37	78	
LS Mean (StdErr) [2]	-1.31 (0.313)	-1.64 (0.244)	-0.70 (0.345)	-1.20 (0.254)	
95% CI [2]	-1.93, -0.68	-2.12, -1.15	-1.39, -0.02	-1.70, -0.69	
Difference (95% CI) in CFB [2]		-0.33 (-1.04, 0.37)		-0.50 (-1.26, 0.26)	
p-value [3]		0.353		0.198	

Headache Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	30	57	36	76	
Mean (StdDev)	3.19 (2.750)	2.45 (2.053)	3.24 (2.474)	2.81 (2.577)	
Median	2.14	1.86	3.04	2.21	
Min, Max	0.0, 8.9	0.0, 8.3	0.0, 7.9	0.0, 10.0	
C7D1 CFB					
n	30	55	36	76	
LS Mean (StdErr) [2]	-1.15 (0.349)	-1.72 (0.280)	-0.65 (0.332)	-1.11 (0.243)	
95% CI [2]	-1.85, -0.46	-2.27, -1.16	-1.31, 0.01	-1.59, -0.62	
Difference (95% CI) in CFB [2]		-0.57 (-1.35, 0.22)		-0.46 (-1.19, 0.27)	
Hedges'G (95% CI) in CFB		-0.28 (-0.74, 0.17)		-0.22 (-0.62, 0.18)	
p-value [3]		0.155		0.218	
					0.852

Diarrhea Count					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	33	58	38	81	
Mean (StdDev)	1.49 (1.453)	1.63 (1.950)	1.50 (1.513)	1.31 (1.386)	
Median	0.93	0.96	1.15	1.00	
Min, Max	0.0, 6.1	0.0, 12.2	0.0, 7.2	0.0, 5.6	

Diarrhea Count	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	33	59	38	78	
Mean (StdDev)	1.37 (1.439)	1.31 (1.683)	1.11 (1.120)	0.94 (1.154)	
Median	0.57	0.92	0.68	0.43	
Min, Max	0.0, 4.9	0.0, 10.7	0.0, 3.8	0.0, 4.3	
C2D1 CFB					
n	33	57	38	78	
LS Mean (StdErr) [2]	-0.26 (0.167)	-0.47 (0.139)	-0.40 (0.140)	-0.41 (0.104)	
95% CI [2]	-0.60, 0.07	-0.75, -0.20	-0.67, -0.12	-0.61, -0.20	
Difference (95% CI) in CFB [2]		-0.21 (-0.59, 0.17)		-0.01 (-0.32, 0.30)	
p-value [3]		0.272		0.946	

Diarrhea Count	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	33	58	38	77	
Mean (StdDev)	1.26 (1.268)	1.07 (1.224)	1.02 (1.070)	0.92 (1.152)	
Median	0.64	0.68	0.77	0.43	
Min, Max	0.0, 4.4	0.0, 5.6	0.0, 3.7	0.0, 5.8	
C3D1 CFB					
n	33	56	38	77	
LS Mean (StdErr) [2]	-0.45 (0.224)	-0.79 (0.188)	-0.49 (0.176)	-0.43 (0.132)	
95% CI [2]	-0.90, -0.01	-1.16, -0.41	-0.84, -0.14	-0.69, -0.17	
Difference (95% CI) in CFB [2]		-0.33 (-0.84, 0.18)		0.06 (-0.33, 0.45)	
p-value [3]		0.196		0.762	

Diarrhea Count	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	31	58	37	77	
Mean (StdDev)	1.13 (1.178)	1.18 (1.653)	1.11 (1.111)	0.85 (1.090)	
Median	0.71	0.64	0.77	0.31	
Min, Max	0.0, 4.3	0.0, 9.0	0.0, 4.8	0.0, 5.4	
C4D1 CFB					
n	31	56	37	77	
LS Mean (StdErr) [2]	-0.59 (0.205)	-0.63 (0.166)	-0.43 (0.184)	-0.50 (0.137)	
95% CI [2]	-1.00, -0.18	-0.96, -0.30	-0.80, -0.07	-0.77, -0.23	
Difference (95% CI) in CFB [2]		-0.04 (-0.50, 0.42)		-0.07 (-0.47, 0.34)	
p-value [3]		0.855		0.742	

Diarrhea Count	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	30	59	37	78	
Mean (StdDev)	1.13 (1.205)	1.22 (1.636)	1.14 (1.190)	0.82 (1.247)	
Median	0.57	0.73	0.79	0.38	
Min, Max	0.0, 4.0	0.0, 9.6	0.0, 4.8	0.0, 8.1	
C5D1 CFB					
n	30	57	37	78	
LS Mean (StdErr) [2]	-0.52 (0.211)	-0.57 (0.164)	-0.46 (0.226)	-0.59 (0.167)	
95% CI [2]	-0.94, -0.10	-0.89, -0.24	-0.91, -0.01	-0.92, -0.26	
Difference (95% CI) in CFB [2]		-0.05 (-0.52, 0.42)		-0.13 (-0.62, 0.37)	
p-value [3]		0.833		0.610	

Diarrhea Count	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	29	58	37	78	
Mean (StdDev)	0.91 (1.023)	1.10 (1.606)	1.16 (1.435)	0.77 (0.961)	
Median	0.50	0.50	0.67	0.39	
Min, Max	0.0, 3.4	0.0, 9.0	0.0, 6.5	0.0, 3.9	
C6D1 CFB					
n	29	56	37	78	
LS Mean (StdErr) [2]	-0.65 (0.202)	-0.67 (0.157)	-0.38 (0.181)	-0.54 (0.133)	
95% CI [2]	-1.06, -0.25	-0.99, -0.36	-0.74, -0.02	-0.81, -0.28	
Difference (95% CI) in CFB [2]		-0.02 (-0.47, 0.44)		-0.16 (-0.56, 0.24)	
p-value [3]		0.939		0.428	

Diarrhea Count	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	30	57	36	76	
Mean (StdDev)	1.01 (1.225)	0.87 (1.203)	1.07 (1.263)	0.80 (1.025)	
Median	0.39	0.23	0.59	0.30	
Min, Max	0.0, 4.1	0.0, 4.8	0.0, 5.9	0.0, 4.2	
C7D1 CFB					
n	30	55	36	76	
LS Mean (StdErr) [2]	-0.49 (0.221)	-0.61 (0.177)	-0.46 (0.198)	-0.59 (0.145)	
95% CI [2]	-0.93, -0.05	-0.96, -0.25	-0.85, -0.07	-0.88, -0.30	
Difference (95% CI) in CFB [2]		-0.12 (-0.61, 0.38)		-0.13 (-0.56, 0.31)	
Hedges'G (95% CI) in CFB		-0.09 (-0.55, 0.36)		-0.10 (-0.51, 0.30)	
p-value [3]		0.638		0.558	
					0.944

Diarrhea Severity					
	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	33	58	38	81	
Mean (StdDev)	2.88 (2.657)	2.83 (2.495)	3.23 (2.590)	2.94 (2.337)	
Median	1.79	2.21	2.78	2.79	
Min, Max	0.0, 9.5	0.0, 9.5	0.0, 8.1	0.0, 9.4	

Diarrhea Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	33	59	38	78	
Mean (StdDev)	2.38 (2.547)	2.30 (2.167)	2.37 (2.276)	2.30 (2.469)	
Median	1.36	1.50	2.04	1.14	
Min, Max	0.0, 9.1	0.0, 8.0	0.0, 8.0	0.0, 8.9	
C2D1 CFB					
n	33	57	38	78	
LS Mean (StdErr) [2]	-0.63 (0.223)	-0.73 (0.186)	-0.59 (0.262)	-0.42 (0.196)	
95% CI [2]	-1.07, -0.18	-1.10, -0.36	-1.11, -0.07	-0.81, -0.04	
Difference (95% CI) in CFB [2]		-0.10 (-0.61, 0.40)		0.17 (-0.41, 0.75)	
p-value [3]		0.691		0.563	

Diarrhea Severity

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	33	58	38	77	
Mean (StdDev)	2.36 (2.412)	2.02 (2.090)	2.14 (2.185)	2.15 (2.355)	
Median	1.50	1.18	1.44	1.14	
Min, Max	0.0, 8.7	0.0, 8.1	0.0, 8.0	0.0, 9.5	
C3D1 CFB					
n	33	56	38	77	
LS Mean (StdErr) [2]	-0.68 (0.289)	-1.03 (0.242)	-0.82 (0.314)	-0.56 (0.235)	
95% CI [2]	-1.25, -0.10	-1.52, -0.55	-1.44, -0.20	-1.03, -0.09	
Difference (95% CI) in CFB [2]		-0.36 (-1.02, 0.30)		0.26 (-0.44, 0.95)	
p-value [3]		0.281		0.463	

Diarrhea Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	31	58	37	77	
Mean (StdDev)	2.34 (2.458)	2.09 (2.206)	2.46 (2.283)	1.96 (2.321)	
Median	1.31	1.44	2.14	0.86	
Min, Max	0.0, 8.3	0.0, 8.9	0.0, 8.0	0.0, 8.3	
C4D1 CFB					
n	31	56	37	77	
LS Mean (StdErr) [2]	-0.75 (0.295)	-0.92 (0.239)	-0.61 (0.309)	-0.81 (0.230)	
95% CI [2]	-1.33, -0.16	-1.40, -0.45	-1.23, -0.00	-1.26, -0.35	
Difference (95% CI) in CFB [2]		-0.18 (-0.83, 0.48)		-0.19 (-0.87, 0.49)	
p-value [3]		0.598		0.576	

Diarrhea Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	30	59	37	78	
Mean (StdDev)	2.30 (2.372)	2.04 (2.183)	2.46 (2.369)	1.89 (2.228)	
Median	1.14	1.31	1.86	1.07	
Min, Max	0.0, 8.5	0.0, 8.5	0.0, 8.0	0.0, 9.0	
C5D1 CFB					
n	30	57	37	78	
LS Mean (StdErr) [2]	-0.75 (0.332)	-0.91 (0.259)	-0.67 (0.352)	-0.96 (0.261)	
95% CI [2]	-1.41, -0.09	-1.43, -0.40	-1.36, 0.03	-1.48, -0.44	
Difference (95% CI) in CFB [2]		-0.16 (-0.90, 0.58)		-0.29 (-1.07, 0.48)	
p-value [3]		0.664		0.452	

Diarrhea Severity

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	29	58	37	78	
Mean (StdDev)	2.05 (2.462)	1.83 (2.095)	2.30 (2.261)	1.81 (2.230)	
Median	0.86	1.21	1.75	0.93	
Min, Max	0.0, 8.6	0.0, 8.6	0.0, 8.0	0.0, 8.9	
C6D1 CFB					
n	29	56	37	78	
LS Mean (StdErr) [2]	-0.80 (0.313)	-1.12 (0.244)	-0.67 (0.322)	-0.87 (0.237)	
95% CI [2]	-1.43, -0.18	-1.61, -0.64	-1.31, -0.03	-1.34, -0.40	
Difference (95% CI) in CFB [2]		-0.32 (-1.03, 0.38)		-0.19 (-0.90, 0.51)	
p-value [3]		0.366		0.588	

Diarrhea Severity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	30	57	36	76	
Mean (StdDev)	2.07 (2.613)	1.58 (2.080)	2.29 (2.296)	1.92 (2.265)	
Median	0.96	0.71	1.92	0.71	
Min, Max	0.0, 8.6	0.0, 8.4	0.0, 8.0	0.0, 8.7	
C7D1 CFB					
n	30	55	36	76	
LS Mean (StdErr) [2]	-0.76 (0.344)	-1.15 (0.276)	-0.75 (0.356)	-0.89 (0.261)	
95% CI [2]	-1.44, -0.07	-1.70, -0.60	-1.46, -0.05	-1.41, -0.37	
Difference (95% CI) in CFB [2]		-0.40 (-1.17, 0.37)		-0.13 (-0.92, 0.65)	
Hedges'G (95% CI) in CFB		-0.20 (-0.66, 0.25)		-0.06 (-0.46, 0.34)	
p-value [3]		0.308		0.734	
					0.679

Bone Pain Severity						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Bone Pain Severity						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Bone Pain Severity						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Bone Pain Severity						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Bone Pain Severity			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abdominal Pain Severity						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abdominal Pain Severity						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abdominal Pain Severity						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abdominal Pain Severity						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abdominal Pain Severity			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Nausea Severity						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Nausea Severity						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Nausea Severity

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Nausea Severity						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Nausea Severity			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Spots Severity						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Spots Severity						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Spots Severity						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Spots Severity						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Spots Severity			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Itching Severity						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Itching Severity						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Itching Severity						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Itching Severity						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Itching Severity			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Flushing Severity						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Flushing Severity						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Flushing Severity						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Flushing Severity						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Flushing Severity			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Fatigue Severity						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Fatigue Severity						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Fatigue Severity						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Fatigue Severity						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Fatigue Severity			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Dizziness Severity						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Dizziness Severity						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Dizziness Severity						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Dizziness Severity						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Dizziness Severity			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Brain Fog Severity						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Brain Fog Severity						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Brain Fog Severity						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Brain Fog Severity						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Brain Fog Severity			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Headache Severity						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Headache Severity						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Headache Severity						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Headache Severity						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Headache Severity			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Diarrhea Count						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Diarrhea Count						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Diarrhea Count						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Diarrhea Count						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Diarrhea Count			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Diarrhea Severity						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Diarrhea Severity						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Diarrhea Severity						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Diarrhea Severity						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Diarrhea Severity			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Bone Pain Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	26	52	45	87	
Mean (StdDev)	3.52 (2.132)	3.33 (2.101)	6.49 (1.897)	6.43 (2.134)	
Median	3.63	3.00	6.69	6.58	
Min, Max	0.0, 8.2	0.0, 8.4	0.7, 10.0	0.0, 10.0	

Bone Pain Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	26	50	45	85	
Mean (StdDev)	3.01 (1.959)	2.83 (2.044)	5.85 (2.296)	5.52 (2.556)	
Median	2.93	2.55	6.21	5.86	
Min, Max	0.0, 7.6	0.0, 8.1	0.5, 10.0	0.0, 10.0	
C2D1 CFB					
n	26	50	45	85	
LS Mean (StdErr) [2]	-0.58 (0.241)	-0.55 (0.178)	-0.60 (0.207)	-0.87 (0.166)	
95% CI [2]	-1.06, -0.10	-0.91, -0.20	-1.01, -0.19	-1.20, -0.54	
Difference (95% CI) in CFB [2]		0.03 (-0.50, 0.56)		-0.27 (-0.74, 0.21)	
p-value [3]		0.917		0.271	

Bone Pain Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	26	50	45	83	
Mean (StdDev)	2.86 (1.857)	2.67 (1.916)	5.71 (2.528)	5.24 (2.740)	
Median	2.87	2.20	6.29	5.14	
Min, Max	0.0, 7.4	0.0, 8.4	0.0, 10.0	0.0, 10.0	
C3D1 CFB					
n	26	50	45	83	
LS Mean (StdErr) [2]	-0.72 (0.300)	-0.71 (0.222)	-0.79 (0.242)	-1.19 (0.195)	
95% CI [2]	-1.31, -0.12	-1.15, -0.26	-1.27, -0.31	-1.57, -0.80	
Difference (95% CI) in CFB [2]		0.01 (-0.65, 0.67)		-0.40 (-0.96, 0.16)	
p-value [3]		0.976		0.159	

Bone Pain Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	24	49	44	84	
Mean (StdDev)	2.79 (1.791)	2.64 (1.918)	5.73 (2.618)	5.20 (2.861)	
Median	2.54	2.07	6.54	5.60	
Min, Max	0.0, 7.2	0.0, 7.5	0.1, 9.8	0.0, 10.0	
C4D1 CFB					
n	24	49	44	84	
LS Mean (StdErr) [2]	-0.62 (0.367)	-0.54 (0.266)	-0.75 (0.285)	-1.18 (0.226)	
95% CI [2]	-1.35, 0.11	-1.07, -0.01	-1.32, -0.19	-1.63, -0.73	
Difference (95% CI) in CFB [2]		0.08 (-0.73, 0.89)		-0.43 (-1.08, 0.22)	
p-value [3]		0.845		0.192	

Bone Pain Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	51	44	84	
Mean (StdDev)	2.57 (1.579)	2.57 (1.960)	5.80 (2.547)	4.92 (2.930)	
Median	3.00	2.36	6.33	4.85	
Min, Max	0.0, 6.1	0.0, 7.6	0.0, 9.8	0.0, 10.0	
C5D1 CFB					
n	23	51	44	84	
LS Mean (StdErr) [2]	-0.63 (0.359)	-0.51 (0.250)	-0.65 (0.314)	-1.44 (0.249)	
95% CI [2]	-1.35, 0.08	-1.01, -0.01	-1.27, -0.03	-1.93, -0.94	
Difference (95% CI) in CFB [2]		0.12 (-0.67, 0.91)		-0.78 (-1.50, -0.07)	
p-value [3]		0.761		0.031	

Bone Pain Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	24	52	42	82	
Mean (StdDev)	3.11 (1.969)	2.51 (1.760)	5.54 (2.705)	4.79 (2.916)	
Median	3.38	2.14	6.12	5.29	
Min, Max	0.0, 6.8	0.0, 6.8	0.0, 9.6	0.0, 10.0	
C6D1 CFB					
n	24	52	42	82	
LS Mean (StdErr) [2]	-0.09 (0.372)	-0.59 (0.261)	-0.84 (0.329)	-1.58 (0.259)	
95% CI [2]	-0.83, 0.65	-1.11, -0.07	-1.49, -0.19	-2.09, -1.07	
Difference (95% CI) in CFB [2]		-0.50 (-1.32, 0.32)		-0.74 (-1.49, 0.01)	
p-value [3]		0.225		0.054	

Bone Pain Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	23	51	43	80	
Mean (StdDev)	3.05 (1.903)	2.54 (1.682)	5.44 (2.708)	4.67 (3.037)	
Median	3.29	2.21	6.00	4.86	
Min, Max	0.0, 7.0	0.0, 7.4	0.0, 9.4	0.0, 10.0	
C7D1 CFB					
n	23	51	43	80	
LS Mean (StdErr) [2]	-0.21 (0.354)	-0.60 (0.246)	-1.00 (0.347)	-1.68 (0.279)	
95% CI [2]	-0.92, 0.49	-1.09, -0.11	-1.68, -0.31	-2.23, -1.12	
Difference (95% CI) in CFB [2]		-0.38 (-1.16, 0.40)		-0.68 (-1.47, 0.11)	
Hedges'G (95% CI) in CFB		-0.22 (-0.73, 0.28)		-0.28 (-0.66, 0.09)	
p-value [3]		0.331		0.092	
					0.614

Abdominal Pain Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	26	52	45	87	
Mean (StdDev)	2.11 (1.777)	2.35 (1.493)	5.07 (2.165)	4.79 (2.171)	
Median	1.85	2.22	4.86	4.77	
Min, Max	0.0, 6.4	0.0, 6.1	0.0, 9.6	0.5, 9.8	

Abdominal Pain Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	26	50	45	85	
Mean (StdDev)	1.83 (1.491)	1.74 (1.379)	4.05 (2.159)	3.96 (2.151)	
Median	1.45	1.50	3.71	3.92	
Min, Max	0.0, 4.7	0.0, 6.0	0.2, 8.9	0.1, 9.4	
C2D1 CFB					
n	26	50	45	85	
LS Mean (StdErr) [2]	-0.21 (0.209)	-0.47 (0.155)	-1.01 (0.191)	-0.86 (0.154)	
95% CI [2]	-0.63, 0.21	-0.78, -0.17	-1.39, -0.64	-1.16, -0.55	
Difference (95% CI) in CFB [2]		-0.26 (-0.72, 0.20)		0.16 (-0.28, 0.60)	
p-value [3]		0.259		0.482	

Abdominal Pain Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	26	50	45	83	
Mean (StdDev)	1.78 (1.559)	1.67 (1.607)	3.79 (2.245)	3.40 (2.230)	
Median	1.53	1.12	3.69	3.21	
Min, Max	0.0, 5.1	0.0, 7.4	0.0, 8.4	0.0, 8.3	
C3D1 CFB					
n	26	50	45	83	
LS Mean (StdErr) [2]	-0.33 (0.278)	-0.60 (0.206)	-1.27 (0.239)	-1.41 (0.193)	
95% CI [2]	-0.89, 0.22	-1.01, -0.19	-1.75, -0.80	-1.79, -1.02	
Difference (95% CI) in CFB [2]		-0.27 (-0.88, 0.34)		-0.13 (-0.69, 0.42)	
p-value [3]		0.386		0.630	

Abdominal Pain Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	24	49	44	84	
Mean (StdDev)	1.62 (1.590)	1.36 (1.331)	3.78 (2.110)	3.17 (2.317)	
Median	1.11	1.00	3.77	3.07	
Min, Max	0.0, 5.6	0.0, 4.7	0.0, 7.9	0.0, 9.1	
C4D1 CFB					
n	24	49	44	84	
LS Mean (StdErr) [2]	-0.37 (0.287)	-0.76 (0.208)	-1.38 (0.298)	-1.72 (0.236)	
95% CI [2]	-0.94, 0.21	-1.17, -0.34	-1.97, -0.79	-2.19, -1.25	
Difference (95% CI) in CFB [2]		-0.39 (-1.02, 0.24)		-0.34 (-1.02, 0.33)	
p-value [3]		0.224		0.316	

Abdominal Pain Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	51	44	84	
Mean (StdDev)	1.81 (1.808)	1.37 (1.526)	3.78 (2.114)	3.01 (2.416)	
Median	1.57	0.93	3.86	2.70	
Min, Max	0.0, 5.6	0.0, 7.0	0.0, 8.1	0.0, 9.4	
C5D1 CFB					
n	23	51	44	84	
LS Mean (StdErr) [2]	-0.12 (0.343)	-0.75 (0.239)	-1.40 (0.319)	-1.90 (0.253)	
95% CI [2]	-0.80, 0.57	-1.22, -0.27	-2.03, -0.77	-2.40, -1.40	
Difference (95% CI) in CFB [2]		-0.63 (-1.38, 0.12)		-0.50 (-1.22, 0.22)	
p-value [3]		0.100		0.174	

Abdominal Pain Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	24	52	42	82	
Mean (StdDev)	1.56 (1.547)	1.38 (1.533)	3.19 (2.134)	2.82 (2.432)	
Median	1.14	1.00	3.07	2.61	
Min, Max	0.0, 5.1	0.0, 7.4	0.0, 7.1	0.0, 9.6	
C6D1 CFB					
n	24	52	42	82	
LS Mean (StdErr) [2]	-0.25 (0.284)	-0.86 (0.199)	-1.90 (0.348)	-2.03 (0.273)	
95% CI [2]	-0.82, 0.31	-1.26, -0.46	-2.59, -1.21	-2.57, -1.49	
Difference (95% CI) in CFB [2]		-0.61 (-1.23, 0.02)		-0.12 (-0.92, 0.67)	
p-value [3]		0.056		0.756	

Abdominal Pain Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	23	51	43	80	
Mean (StdDev)	1.36 (1.503)	1.36 (1.429)	3.53 (2.295)	2.88 (2.382)	
Median	1.00	1.00	3.23	2.76	
Min, Max	0.0, 5.4	0.0, 5.4	0.0, 8.3	0.0, 9.4	
C7D1 CFB					
n	23	51	43	80	
LS Mean (StdErr) [2]	-0.35 (0.278)	-0.81 (0.194)	-1.65 (0.339)	-2.00 (0.273)	
95% CI [2]	-0.90, 0.21	-1.20, -0.42	-2.32, -0.98	-2.54, -1.46	
Difference (95% CI) in CFB [2]		-0.46 (-1.07, 0.15)		-0.35 (-1.13, 0.42)	
Hedges'G (95% CI) in CFB		-0.33 (-0.85, 0.16)		-0.15 (-0.53, 0.22)	
p-value [3]		0.138		0.370	
					0.867

Nausea Severity

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	26	52	45	87	
Mean (StdDev)	1.41 (1.374)	1.33 (1.378)	4.49 (2.312)	3.90 (2.602)	
Median	0.93	0.96	4.86	3.85	
Min, Max	0.0, 4.1	0.0, 4.9	0.0, 8.9	0.0, 9.0	

Nausea Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	26	50	45	85	
Mean (StdDev)	1.40 (1.420)	1.13 (1.194)	3.71 (2.401)	3.35 (2.453)	
Median	0.75	0.71	3.69	3.29	
Min, Max	0.0, 4.1	0.0, 4.1	0.0, 8.3	0.0, 8.8	
C2D1 CFB					
n	26	50	45	85	
LS Mean (StdErr) [2]	0.12 (0.196)	-0.02 (0.145)	-0.81 (0.217)	-0.61 (0.174)	
95% CI [2]	-0.27, 0.51	-0.31, 0.27	-1.24, -0.38	-0.95, -0.26	
Difference (95% CI) in CFB [2]		-0.14 (-0.57, 0.29)		0.21 (-0.29, 0.70)	
p-value [3]		0.512		0.413	

Nausea Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	26	50	45	83	
Mean (StdDev)	1.21 (1.244)	1.10 (1.059)	3.29 (2.433)	2.96 (2.476)	
Median	0.88	1.06	2.77	2.71	
Min, Max	0.0, 3.6	0.0, 3.4	0.0, 7.7	0.0, 8.9	
C3D1 CFB					
n	26	50	45	83	
LS Mean (StdErr) [2]	-0.08 (0.214)	-0.07 (0.158)	-1.32 (0.265)	-1.09 (0.214)	
95% CI [2]	-0.51, 0.34	-0.38, 0.25	-1.84, -0.79	-1.52, -0.67	
Difference (95% CI) in CFB [2]		0.02 (-0.45, 0.49)		0.22 (-0.39, 0.84)	
p-value [3]		0.947		0.468	

Nausea Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	24	49	44	84	
Mean (StdDev)	1.30 (1.409)	0.76 (0.871)	3.30 (2.308)	2.68 (2.444)	
Median	0.86	0.36	3.14	2.11	
Min, Max	0.0, 4.3	0.0, 2.9	0.0, 7.4	0.0, 9.2	
C4D1 CFB					
n	24	49	44	84	
LS Mean (StdErr) [2]	-0.09 (0.246)	-0.40 (0.178)	-1.40 (0.298)	-1.44 (0.236)	
95% CI [2]	-0.58, 0.41	-0.76, -0.05	-1.99, -0.81	-1.91, -0.98	
Difference (95% CI) in CFB [2]		-0.32 (-0.86, 0.23)		-0.04 (-0.72, 0.63)	
p-value [3]		0.249		0.902	

Nausea Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	51	44	84	
Mean (StdDev)	1.35 (1.343)	0.89 (0.984)	3.32 (2.310)	2.61 (2.487)	
Median	0.79	0.36	3.09	2.11	
Min, Max	0.0, 4.1	0.0, 3.2	0.0, 8.5	0.0, 8.9	
C5D1 CFB					
n	23	51	44	84	
LS Mean (StdErr) [2]	0.02 (0.247)	-0.24 (0.172)	-1.42 (0.328)	-1.56 (0.260)	
95% CI [2]	-0.47, 0.52	-0.58, 0.10	-2.07, -0.77	-2.08, -1.05	
Difference (95% CI) in CFB [2]		-0.26 (-0.81, 0.28)		-0.14 (-0.89, 0.60)	
p-value [3]		0.335		0.705	

Nausea Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	24	52	42	82	
Mean (StdDev)	1.35 (1.542)	0.75 (0.915)	2.86 (2.224)	2.40 (2.437)	
Median	0.68	0.18	2.46	1.71	
Min, Max	0.0, 4.1	0.0, 3.3	0.0, 7.9	0.0, 9.9	
C6D1 CFB					
n	24	52	42	82	
LS Mean (StdErr) [2]	0.01 (0.263)	-0.53 (0.185)	-1.91 (0.328)	-1.72 (0.257)	
95% CI [2]	-0.52, 0.53	-0.90, -0.16	-2.56, -1.26	-2.23, -1.21	
Difference (95% CI) in CFB [2]		-0.54 (-1.12, 0.04)		0.19 (-0.56, 0.93)	
p-value [3]		0.067		0.622	

Nausea Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	23	51	43	80	
Mean (StdDev)	1.15 (1.457)	0.87 (0.969)	3.08 (2.363)	2.39 (2.444)	
Median	0.56	0.43	3.21	1.63	
Min, Max	0.0, 4.6	0.0, 3.1	0.0, 7.7	0.0, 9.5	
C7D1 CFB					
n	23	51	43	80	
LS Mean (StdErr) [2]	-0.04 (0.261)	-0.32 (0.181)	-1.74 (0.358)	-1.78 (0.288)	
95% CI [2]	-0.56, 0.48	-0.68, 0.04	-2.45, -1.03	-2.35, -1.21	
Difference (95% CI) in CFB [2]		-0.28 (-0.86, 0.29)		-0.04 (-0.86, 0.78)	
Hedges'G (95% CI) in CFB		-0.22 (-0.73, 0.28)		-0.01 (-0.39, 0.36)	
p-value [3]		0.331		0.930	
					0.703

Spots Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	26	52	45	87	
Mean (StdDev)	4.09 (3.363)	3.76 (2.421)	6.74 (2.564)	6.21 (3.005)	
Median	3.57	3.93	7.07	6.64	
Min, Max	0.0, 10.0	0.0, 8.2	0.0, 10.0	0.0, 10.0	

Spots Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	26	50	45	85	
Mean (StdDev)	3.94 (3.169)	3.15 (2.359)	6.23 (2.487)	5.17 (2.746)	
Median	2.96	3.04	6.57	5.29	
Min, Max	0.0, 10.0	0.0, 7.5	0.0, 10.0	0.0, 10.0	
C2D1 CFB					
n	26	50	45	85	
LS Mean (StdErr) [2]	-0.12 (0.203)	-0.59 (0.151)	-0.52 (0.220)	-1.06 (0.177)	
95% CI [2]	-0.53, 0.28	-0.89, -0.29	-0.95, -0.08	-1.42, -0.71	
Difference (95% CI) in CFB [2]		-0.46 (-0.91, -0.02)		-0.55 (-1.06, -0.04)	
p-value [3]		0.042		0.034	

Spots Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	26	50	45	83	
Mean (StdDev)	3.97 (3.216)	2.97 (2.323)	6.15 (2.555)	4.65 (2.616)	
Median	2.81	2.77	5.86	4.29	
Min, Max	0.0, 10.0	0.0, 7.0	0.0, 10.0	0.0, 9.8	
C3D1 CFB					
n	26	50	45	83	
LS Mean (StdErr) [2]	-0.06 (0.295)	-0.75 (0.218)	-0.55 (0.257)	-1.57 (0.207)	
95% CI [2]	-0.65, 0.52	-1.18, -0.31	-1.05, -0.04	-1.98, -1.16	
Difference (95% CI) in CFB [2]		-0.68 (-1.33, -0.03)		-1.02 (-1.62, -0.43)	
p-value [3]		0.039		<0.001	

Spots Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	24	49	44	84	
Mean (StdDev)	3.71 (3.196)	2.81 (2.272)	6.08 (2.576)	4.39 (2.641)	
Median	2.32	2.00	6.21	4.00	
Min, Max	0.0, 10.0	0.0, 7.1	0.0, 10.0	0.0, 9.4	
C4D1 CFB					
n	24	49	44	84	
LS Mean (StdErr) [2]	0.04 (0.244)	-0.85 (0.177)	-0.53 (0.290)	-1.69 (0.230)	
95% CI [2]	-0.44, 0.53	-1.21, -0.50	-1.10, 0.04	-2.14, -1.23	
Difference (95% CI) in CFB [2]		-0.90 (-1.43, -0.36)		-1.16 (-1.82, -0.50)	
p-value [3]		0.001		<0.001	

Spots Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	51	44	84	
Mean (StdDev)	3.64 (3.208)	2.67 (2.081)	5.90 (2.657)	4.18 (2.683)	
Median	3.07	2.14	5.43	3.73	
Min, Max	0.0, 10.0	0.0, 7.0	0.0, 10.0	0.0, 9.9	
C5D1 CFB					
n	23	51	44	84	
LS Mean (StdErr) [2]	-0.06 (0.285)	-1.08 (0.199)	-0.76 (0.308)	-1.94 (0.244)	
95% CI [2]	-0.63, 0.50	-1.47, -0.68	-1.37, -0.15	-2.43, -1.46	
Difference (95% CI) in CFB [2]		-1.01 (-1.64, -0.38)		-1.18 (-1.88, -0.48)	
p-value [3]		0.002		0.001	

Spots Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	24	52	42	82	
Mean (StdDev)	3.82 (3.158)	2.54 (2.001)	5.98 (2.715)	4.04 (2.735)	
Median	3.43	2.00	5.43	3.69	
Min, Max	0.0, 10.0	0.0, 6.9	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	24	52	42	82	
LS Mean (StdErr) [2]	-0.14 (0.293)	-1.18 (0.206)	-0.52 (0.370)	-1.95 (0.290)	
95% CI [2]	-0.73, 0.44	-1.59, -0.77	-1.25, 0.21	-2.52, -1.37	
Difference (95% CI) in CFB [2]		-1.03 (-1.68, -0.39)		-1.43 (-2.27, -0.58)	
p-value [3]		0.002		0.001	

Spots Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	23	51	43	80	
Mean (StdDev)	4.03 (2.994)	2.60 (2.095)	5.87 (2.796)	3.99 (2.831)	
Median	4.00	2.00	5.46	3.51	
Min, Max	0.0, 10.0	0.0, 6.7	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	23	51	43	80	
LS Mean (StdErr) [2]	-0.16 (0.268)	-1.17 (0.187)	-0.69 (0.378)	-2.07 (0.304)	
95% CI [2]	-0.69, 0.37	-1.54, -0.80	-1.43, 0.06	-2.67, -1.47	
Difference (95% CI) in CFB [2]		-1.01 (-1.60, -0.42)		-1.39 (-2.25, -0.52)	
Hedges'G (95% CI) in CFB		-0.76 (-1.30, -0.26)		-0.52 (-0.91, -0.15)	
p-value [3]		0.001		0.002	
					0.559

Itching Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	26	52	45	87	
Mean (StdDev)	3.72 (2.645)	3.30 (2.331)	6.86 (2.176)	6.23 (2.478)	
Median	3.55	2.97	7.00	6.38	
Min, Max	0.0, 9.0	0.0, 8.4	1.2, 10.0	0.0, 10.0	

Itching Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	26	50	45	85	
Mean (StdDev)	3.23 (2.597)	2.43 (2.129)	6.14 (2.344)	5.02 (2.153)	
Median	2.36	2.00	6.29	4.92	
Min, Max	0.0, 8.9	0.0, 7.3	1.1, 10.0	0.1, 9.9	
C2D1 CFB					
n	26	50	45	85	
LS Mean (StdErr) [2]	-0.59 (0.286)	-0.91 (0.212)	-0.77 (0.274)	-1.29 (0.220)	
95% CI [2]	-1.16, -0.02	-1.34, -0.49	-1.31, -0.22	-1.73, -0.85	
Difference (95% CI) in CFB [2]		-0.32 (-0.95, 0.31)		-0.52 (-1.15, 0.11)	
p-value [3]		0.311		0.103	

Itching Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	26	50	45	83	
Mean (StdDev)	3.08 (2.554)	2.26 (1.984)	5.76 (2.493)	4.19 (2.485)	
Median	2.71	1.93	5.71	3.86	
Min, Max	0.0, 9.0	0.0, 6.7	0.9, 10.0	0.0, 9.7	
C3D1 CFB					
n	26	50	45	83	
LS Mean (StdErr) [2]	-0.83 (0.366)	-1.15 (0.271)	-1.07 (0.330)	-2.05 (0.267)	
95% CI [2]	-1.56, -0.10	-1.69, -0.61	-1.73, -0.42	-2.57, -1.52	
Difference (95% CI) in CFB [2]		-0.33 (-1.13, 0.48)		-0.97 (-1.74, -0.21)	
p-value [3]		0.423		0.013	

Itching Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	24	49	44	84	
Mean (StdDev)	2.72 (2.485)	1.97 (1.853)	5.74 (2.503)	3.97 (2.656)	
Median	2.11	1.38	5.74	3.64	
Min, Max	0.0, 7.9	0.0, 6.7	0.0, 10.0	0.0, 10.0	
C4D1 CFB					
n	24	49	44	84	
LS Mean (StdErr) [2]	-1.06 (0.339)	-1.42 (0.246)	-1.14 (0.410)	-2.26 (0.325)	
95% CI [2]	-1.74, -0.39	-1.91, -0.93	-1.95, -0.32	-2.90, -1.61	
Difference (95% CI) in CFB [2]		-0.36 (-1.10, 0.39)		-1.12 (-2.05, -0.19)	
p-value [3]		0.345		0.019	

Itching Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	51	44	84	
Mean (StdDev)	3.14 (2.421)	1.98 (1.704)	5.62 (2.572)	3.64 (2.728)	
Median	2.79	1.93	5.52	3.30	
Min, Max	0.0, 7.2	0.0, 6.7	0.1, 10.0	0.0, 10.0	
C5D1 CFB					
n	23	51	44	84	
LS Mean (StdErr) [2]	-0.70 (0.364)	-1.43 (0.254)	-1.26 (0.423)	-2.58 (0.335)	
95% CI [2]	-1.42, 0.03	-1.93, -0.92	-2.09, -0.42	-3.24, -1.92	
Difference (95% CI) in CFB [2]		-0.73 (-1.53, 0.07)		-1.32 (-2.28, -0.36)	
p-value [3]		0.074		0.007	

Itching Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	24	52	42	82	
Mean (StdDev)	3.10 (2.154)	1.98 (1.640)	5.64 (2.646)	3.60 (2.785)	
Median	3.38	1.85	5.71	3.00	
Min, Max	0.0, 7.5	0.0, 6.4	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	24	52	42	82	
LS Mean (StdErr) [2]	-0.76 (0.411)	-1.36 (0.289)	-1.29 (0.431)	-2.77 (0.338)	
95% CI [2]	-1.58, 0.06	-1.93, -0.78	-2.14, -0.43	-3.44, -2.10	
Difference (95% CI) in CFB [2]		-0.60 (-1.50, 0.31)		-1.48 (-2.46, -0.49)	
p-value [3]		0.192		0.004	

Itching Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	23	51	43	80	
Mean (StdDev)	3.29 (2.096)	2.13 (1.795)	5.66 (2.557)	3.46 (2.754)	
Median	2.86	2.00	5.86	3.28	
Min, Max	0.0, 7.0	0.0, 7.5	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	23	51	43	80	
LS Mean (StdErr) [2]	-0.79 (0.391)	-1.27 (0.272)	-1.28 (0.447)	-2.90 (0.360)	
95% CI [2]	-1.57, -0.01	-1.81, -0.73	-2.16, -0.39	-3.61, -2.18	
Difference (95% CI) in CFB [2]		-0.48 (-1.34, 0.39)		-1.62 (-2.64, -0.59)	
Hedges'G (95% CI) in CFB		-0.24 (-0.75, 0.25)		-0.51 (-0.90, -0.14)	
p-value [3]		0.275		0.002	
					0.133

Flushing Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	26	52	45	87	
Mean (StdDev)	4.21 (2.451)	3.15 (2.315)	6.58 (2.393)	6.22 (1.870)	
Median	3.83	3.00	6.42	6.00	
Min, Max	0.0, 9.0	0.0, 7.6	0.0, 10.0	2.9, 10.0	

Flushing Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	26	50	45	85	
Mean (StdDev)	3.61 (2.475)	2.70 (2.257)	6.07 (2.457)	5.36 (2.146)	
Median	2.92	2.04	5.73	5.29	
Min, Max	0.0, 8.9	0.0, 7.4	0.0, 10.0	0.5, 10.0	
C2D1 CFB					
n	26	50	45	85	
LS Mean (StdErr) [2]	-0.71 (0.284)	-0.50 (0.210)	-0.53 (0.247)	-0.92 (0.198)	
95% CI [2]	-1.28, -0.15	-0.92, -0.08	-1.02, -0.04	-1.31, -0.52	
Difference (95% CI) in CFB [2]		0.21 (-0.41, 0.83)		-0.38 (-0.95, 0.18)	
p-value [3]		0.504		0.184	

Flushing Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	26	50	45	83	
Mean (StdDev)	3.44 (2.479)	2.54 (2.042)	5.87 (2.718)	4.74 (2.386)	
Median	2.55	2.17	5.50	4.80	
Min, Max	0.0, 8.5	0.0, 7.4	0.0, 10.0	0.0, 10.0	
C3D1 CFB					
n	26	50	45	83	
LS Mean (StdErr) [2]	-0.93 (0.348)	-0.70 (0.257)	-0.66 (0.291)	-1.49 (0.235)	
95% CI [2]	-1.63, -0.24	-1.21, -0.19	-1.24, -0.08	-1.95, -1.02	
Difference (95% CI) in CFB [2]		0.23 (-0.53, 0.99)		-0.83 (-1.50, -0.16)	
p-value [3]		0.547		0.016	

Flushing Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	24	49	44	84	
Mean (StdDev)	3.30 (2.349)	2.31 (1.897)	5.89 (2.761)	4.51 (2.501)	
Median	2.82	2.00	5.86	4.78	
Min, Max	0.0, 8.0	0.0, 6.9	0.1, 10.0	0.0, 10.0	
C4D1 CFB					
n	24	49	44	84	
LS Mean (StdErr) [2]	-0.91 (0.421)	-0.84 (0.305)	-0.73 (0.329)	-1.79 (0.260)	
95% CI [2]	-1.75, -0.07	-1.44, -0.23	-1.38, -0.08	-2.31, -1.28	
Difference (95% CI) in CFB [2]		0.07 (-0.86, 1.00)		-1.07 (-1.81, -0.32)	
p-value [3]		0.877		0.006	

Flushing Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	51	44	84	
Mean (StdDev)	3.26 (2.474)	2.31 (1.967)	5.84 (2.769)	4.34 (2.505)	
Median	2.50	2.00	5.78	4.38	
Min, Max	0.0, 8.0	0.0, 6.8	0.0, 10.0	0.0, 9.8	
C5D1 CFB					
n	23	51	44	84	
LS Mean (StdErr) [2]	-0.98 (0.442)	-0.95 (0.308)	-0.83 (0.375)	-2.03 (0.298)	
95% CI [2]	-1.86, -0.10	-1.56, -0.33	-1.58, -0.09	-2.62, -1.44	
Difference (95% CI) in CFB [2]		0.03 (-0.94, 1.01)		-1.20 (-2.05, -0.35)	
p-value [3]		0.948		0.006	

Flushing Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	24	52	42	82	
Mean (StdDev)	3.46 (2.393)	2.12 (1.830)	5.62 (2.951)	4.25 (2.571)	
Median	3.55	1.54	5.58	4.19	
Min, Max	0.0, 8.0	0.0, 6.5	0.1, 10.0	0.0, 10.0	
C6D1 CFB					
n	24	52	42	82	
LS Mean (StdErr) [2]	-0.93 (0.438)	-1.04 (0.308)	-1.02 (0.395)	-2.19 (0.310)	
95% CI [2]	-1.80, -0.06	-1.65, -0.43	-1.80, -0.23	-2.81, -1.58	
Difference (95% CI) in CFB [2]		-0.11 (-1.07, 0.85)		-1.18 (-2.08, -0.27)	
p-value [3]		0.818		0.011	

Flushing Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	23	51	43	80	
Mean (StdDev)	3.61 (2.202)	2.21 (1.917)	5.61 (2.974)	3.93 (2.565)	
Median	3.79	1.64	5.93	3.68	
Min, Max	0.0, 8.0	0.0, 7.2	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	23	51	43	80	
LS Mean (StdErr) [2]	-0.91 (0.479)	-0.89 (0.333)	-1.00 (0.392)	-2.41 (0.316)	
95% CI [2]	-1.86, 0.05	-1.55, -0.22	-1.78, -0.23	-3.04, -1.79	
Difference (95% CI) in CFB [2]		0.02 (-1.03, 1.07)		-1.41 (-2.31, -0.51)	
Hedges'G (95% CI) in CFB		0.01 (-0.49, 0.51)		-0.51 (-0.90, -0.14)	
p-value [3]		0.969		0.002	
					0.047

Fatigue Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	26	52	45	87	
Mean (StdDev)	5.45 (1.975)	4.99 (1.805)	7.45 (1.652)	7.65 (1.611)	
Median	5.50	5.07	7.21	7.69	
Min, Max	0.0, 8.4	0.1, 8.8	3.8, 10.0	2.8, 10.0	

Fatigue Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	26	50	45	85	
Mean (StdDev)	5.16 (1.759)	4.33 (1.847)	6.96 (1.804)	6.92 (2.033)	
Median	4.89	4.35	6.91	7.00	
Min, Max	2.3, 8.3	0.1, 7.8	2.8, 10.0	1.0, 10.0	
C2D1 CFB					
n	26	50	45	85	
LS Mean (StdErr) [2]	-0.38 (0.245)	-0.73 (0.181)	-0.52 (0.201)	-0.77 (0.162)	
95% CI [2]	-0.86, 0.11	-1.09, -0.37	-0.92, -0.13	-1.09, -0.45	
Difference (95% CI) in CFB [2]		-0.36 (-0.89, 0.18)		-0.24 (-0.70, 0.22)	
p-value [3]		0.190		0.303	

Fatigue Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	26	50	45	83	
Mean (StdDev)	4.79 (2.139)	4.00 (1.759)	6.57 (2.202)	6.49 (2.191)	
Median	4.39	3.81	6.29	6.50	
Min, Max	0.3, 8.4	0.7, 8.1	0.3, 10.0	0.2, 10.0	
C3D1 CFB					
n	26	50	45	83	
LS Mean (StdErr) [2]	-0.82 (0.334)	-1.13 (0.247)	-0.88 (0.251)	-1.15 (0.203)	
95% CI [2]	-1.48, -0.15	-1.62, -0.63	-1.38, -0.38	-1.55, -0.75	
Difference (95% CI) in CFB [2]		-0.31 (-1.04, 0.42)		-0.27 (-0.85, 0.31)	
p-value [3]		0.404		0.361	

Fatigue Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	24	49	44	84	
Mean (StdDev)	4.54 (2.087)	3.78 (1.838)	6.31 (2.409)	6.15 (2.431)	
Median	4.29	3.46	6.26	6.29	
Min, Max	1.3, 7.9	0.0, 7.7	0.2, 10.0	0.0, 10.0	
C4D1 CFB					
n	24	49	44	84	
LS Mean (StdErr) [2]	-0.85 (0.398)	-1.24 (0.288)	-1.25 (0.313)	-1.61 (0.248)	
95% CI [2]	-1.64, -0.05	-1.82, -0.67	-1.87, -0.63	-2.10, -1.12	
Difference (95% CI) in CFB [2]		-0.40 (-1.27, 0.48)		-0.36 (-1.07, 0.35)	
p-value [3]		0.371		0.323	

Fatigue Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	51	44	84	
Mean (StdDev)	4.09 (1.773)	3.79 (1.920)	6.33 (2.396)	6.08 (2.401)	
Median	4.07	3.57	6.00	6.18	
Min, Max	1.2, 7.4	0.0, 8.0	0.6, 10.0	0.0, 10.0	
C5D1 CFB					
n	23	51	44	84	
LS Mean (StdErr) [2]	-1.05 (0.394)	-1.09 (0.274)	-1.20 (0.330)	-1.64 (0.262)	
95% CI [2]	-1.83, -0.26	-1.64, -0.55	-1.85, -0.55	-2.16, -1.12	
Difference (95% CI) in CFB [2]		-0.05 (-0.92, 0.82)		-0.44 (-1.19, 0.31)	
p-value [3]		0.911		0.246	

Fatigue Severity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	24	52	42	82	
Mean (StdDev)	4.59 (1.971)	3.64 (1.938)	6.19 (2.512)	5.89 (2.702)	
Median	4.32	3.33	6.11	6.18	
Min, Max	1.2, 8.4	0.0, 8.3	0.4, 10.0	0.0, 10.0	
C6D1 CFB					
n	24	52	42	82	
LS Mean (StdErr) [2]	-0.68 (0.430)	-1.36 (0.302)	-1.28 (0.361)	-1.78 (0.283)	
95% CI [2]	-1.54, 0.17	-1.96, -0.76	-2.00, -0.57	-2.34, -1.22	
Difference (95% CI) in CFB [2]		-0.68 (-1.62, 0.27)		-0.50 (-1.33, 0.32)	
p-value [3]		0.157		0.230	

Fatigue Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	23	51	43	80	
Mean (StdDev)	4.36 (1.939)	3.86 (2.016)	6.24 (2.560)	5.54 (2.721)	
Median	4.33	3.45	6.00	5.88	
Min, Max	0.2, 7.7	0.1, 8.4	0.4, 10.0	0.0, 10.0	
C7D1 CFB					
n	23	51	43	80	
LS Mean (StdErr) [2]	-1.01 (0.447)	-1.21 (0.311)	-1.22 (0.359)	-2.09 (0.289)	
95% CI [2]	-1.90, -0.12	-1.83, -0.59	-1.94, -0.51	-2.67, -1.52	
Difference (95% CI) in CFB [2]		-0.20 (-1.19, 0.78)		-0.87 (-1.69, -0.05)	
Hedges'G (95% CI) in CFB		-0.09 (-0.60, 0.41)		-0.34 (-0.73, 0.03)	
p-value [3]		0.682		0.038	
					0.319

Dizziness Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	26	52	45	87	
Mean (StdDev)	2.19 (1.605)	1.34 (1.492)	4.37 (2.982)	5.02 (2.604)	
Median	2.24	0.77	4.00	5.00	
Min, Max	0.0, 6.3	0.0, 5.0	0.0, 9.3	0.0, 10.0	

Dizziness Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	26	50	45	85	
Mean (StdDev)	1.80 (1.637)	1.18 (1.415)	3.88 (2.826)	4.20 (2.626)	
Median	1.78	0.67	3.50	4.00	
Min, Max	0.0, 6.3	0.0, 5.4	0.0, 8.7	0.0, 10.0	
C2D1 CFB					
n	26	50	45	85	
LS Mean (StdErr) [2]	-0.27 (0.227)	-0.08 (0.168)	-0.57 (0.235)	-0.93 (0.189)	
95% CI [2]	-0.72, 0.19	-0.42, 0.25	-1.04, -0.11	-1.30, -0.55	
Difference (95% CI) in CFB [2]		0.18 (-0.32, 0.68)		-0.35 (-0.89, 0.19)	
p-value [3]		0.471		0.197	

Dizziness Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	26	50	45	83	
Mean (StdDev)	1.58 (1.741)	1.08 (1.290)	3.45 (2.722)	3.74 (2.801)	
Median	1.07	0.42	2.54	3.75	
Min, Max	0.0, 6.5	0.0, 5.1	0.0, 8.1	0.0, 10.0	
C3D1 CFB					
n	26	50	45	83	
LS Mean (StdErr) [2]	-0.53 (0.257)	-0.23 (0.190)	-0.99 (0.280)	-1.39 (0.226)	
95% CI [2]	-1.05, -0.02	-0.61, 0.15	-1.54, -0.44	-1.84, -0.94	
Difference (95% CI) in CFB [2]		0.30 (-0.26, 0.87)		-0.40 (-1.04, 0.25)	
p-value [3]		0.288		0.224	

Dizziness Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	24	49	44	84	
Mean (StdDev)	1.94 (1.905)	0.97 (1.222)	3.43 (2.853)	3.63 (2.874)	
Median	1.57	0.56	2.93	3.29	
Min, Max	0.0, 6.7	0.0, 5.2	0.0, 9.9	0.0, 10.0	
C4D1 CFB					
n	24	49	44	84	
LS Mean (StdErr) [2]	-0.08 (0.258)	-0.31 (0.187)	-1.13 (0.346)	-1.58 (0.274)	
95% CI [2]	-0.60, 0.43	-0.68, 0.06	-1.82, -0.45	-2.13, -1.04	
Difference (95% CI) in CFB [2]		-0.23 (-0.80, 0.34)		-0.45 (-1.24, 0.33)	
p-value [3]		0.426		0.256	

Dizziness Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	51	44	84	
Mean (StdDev)	1.76 (1.862)	1.05 (1.389)	3.54 (2.730)	3.40 (2.821)	
Median	1.33	0.23	2.96	2.48	
Min, Max	0.0, 6.8	0.0, 5.4	0.0, 9.6	0.0, 10.0	
C5D1 CFB					
n	23	51	44	84	
LS Mean (StdErr) [2]	-0.20 (0.276)	-0.17 (0.193)	-1.00 (0.335)	-1.78 (0.265)	
95% CI [2]	-0.75, 0.35	-0.55, 0.21	-1.66, -0.33	-2.31, -1.26	
Difference (95% CI) in CFB [2]		0.03 (-0.58, 0.64)		-0.79 (-1.55, -0.02)	
p-value [3]		0.922		0.043	

Dizziness Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	24	52	42	82	
Mean (StdDev)	1.59 (1.788)	1.02 (1.321)	3.33 (2.781)	3.09 (2.779)	
Median	0.96	0.22	2.14	2.69	
Min, Max	0.0, 6.0	0.0, 4.8	0.0, 8.6	0.0, 10.0	
C6D1 CFB					
n	24	52	42	82	
LS Mean (StdErr) [2]	-0.44 (0.286)	-0.25 (0.201)	-1.29 (0.365)	-2.15 (0.287)	
95% CI [2]	-1.01, 0.13	-0.65, 0.15	-2.01, -0.57	-2.72, -1.59	
Difference (95% CI) in CFB [2]		0.19 (-0.44, 0.82)		-0.86 (-1.70, -0.03)	
p-value [3]		0.546		0.042	

Dizziness Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	23	51	43	80	
Mean (StdDev)	1.64 (1.722)	1.01 (1.330)	3.30 (2.870)	3.13 (2.805)	
Median	0.93	0.29	2.15	2.57	
Min, Max	0.0, 5.6	0.0, 4.8	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	23	51	43	80	
LS Mean (StdErr) [2]	-0.32 (0.312)	-0.28 (0.217)	-1.39 (0.374)	-2.09 (0.301)	
95% CI [2]	-0.95, 0.30	-0.71, 0.15	-2.13, -0.65	-2.69, -1.50	
Difference (95% CI) in CFB [2]		0.04 (-0.64, 0.73)		-0.71 (-1.56, 0.15)	
Hedges'G (95% CI) in CFB		0.03 (-0.47, 0.53)		-0.27 (-0.65, 0.10)	
p-value [3]		0.899		0.104	
					0.222

Brain Fog Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	26	52	45	87	
Mean (StdDev)	3.23 (2.045)	3.69 (1.773)	6.07 (2.566)	6.39 (2.331)	
Median	3.29	3.54	5.93	6.43	
Min, Max	0.0, 6.9	0.0, 7.1	0.0, 10.0	0.0, 10.0	

Brain Fog Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	26	50	45	85	
Mean (StdDev)	2.85 (1.725)	3.23 (1.850)	5.51 (2.632)	5.59 (2.740)	
Median	2.68	3.21	5.57	5.86	
Min, Max	0.0, 6.5	0.0, 7.0	0.0, 10.0	0.0, 10.0	
C2D1 CFB					
n	26	50	45	85	
LS Mean (StdErr) [2]	-0.46 (0.227)	-0.53 (0.168)	-0.55 (0.194)	-0.78 (0.156)	
95% CI [2]	-0.91, -0.01	-0.87, -0.20	-0.94, -0.17	-1.08, -0.47	
Difference (95% CI) in CFB [2]		-0.07 (-0.57, 0.43)		-0.22 (-0.67, 0.22)	
p-value [3]		0.781		0.321	

Brain Fog Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	26	50	45	83	
Mean (StdDev)	2.79 (1.976)	2.86 (1.768)	5.18 (2.730)	5.31 (2.812)	
Median	2.64	2.71	5.07	5.43	
Min, Max	0.0, 6.8	0.0, 7.0	0.0, 10.0	0.0, 10.0	
C3D1 CFB					
n	26	50	45	83	
LS Mean (StdErr) [2]	-0.62 (0.266)	-0.98 (0.197)	-0.83 (0.233)	-1.05 (0.189)	
95% CI [2]	-1.15, -0.09	-1.37, -0.59	-1.30, -0.37	-1.43, -0.68	
Difference (95% CI) in CFB [2]		-0.36 (-0.94, 0.22)		-0.22 (-0.76, 0.32)	
p-value [3]		0.222		0.419	

Brain Fog Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	24	49	44	84	
Mean (StdDev)	2.45 (1.896)	2.67 (1.945)	4.99 (2.808)	5.03 (2.940)	
Median	2.24	2.46	4.79	5.26	
Min, Max	0.0, 6.9	0.0, 7.0	0.0, 10.0	0.0, 10.0	
C4D1 CFB					
n	24	49	44	84	
LS Mean (StdErr) [2]	-0.79 (0.343)	-1.08 (0.249)	-1.05 (0.287)	-1.35 (0.227)	
95% CI [2]	-1.47, -0.10	-1.57, -0.58	-1.62, -0.49	-1.80, -0.90	
Difference (95% CI) in CFB [2]		-0.29 (-1.04, 0.47)		-0.29 (-0.94, 0.36)	
p-value [3]		0.450		0.377	

Brain Fog Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	51	44	84	
Mean (StdDev)	2.14 (1.711)	2.79 (2.037)	4.84 (2.806)	4.95 (2.991)	
Median	2.21	2.64	4.44	5.07	
Min, Max	0.0, 5.2	0.0, 7.0	0.0, 10.0	0.0, 10.0	
C5D1 CFB					
n	23	51	44	84	
LS Mean (StdErr) [2]	-0.88 (0.359)	-0.88 (0.250)	-1.15 (0.317)	-1.35 (0.251)	
95% CI [2]	-1.59, -0.16	-1.38, -0.38	-1.78, -0.52	-1.85, -0.85	
Difference (95% CI) in CFB [2]		0.00 (-0.79, 0.79)		-0.20 (-0.92, 0.52)	
p-value [3]		>0.999		0.580	

Brain Fog Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	24	52	42	82	
Mean (StdDev)	2.78 (2.188)	2.77 (2.023)	4.65 (2.843)	4.76 (3.111)	
Median	2.85	2.60	4.48	5.11	
Min, Max	0.0, 7.9	0.0, 7.6	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	24	52	42	82	
LS Mean (StdErr) [2]	-0.38 (0.335)	-0.95 (0.236)	-1.33 (0.322)	-1.64 (0.253)	
95% CI [2]	-1.05, 0.28	-1.42, -0.48	-1.97, -0.69	-2.14, -1.14	
Difference (95% CI) in CFB [2]		-0.57 (-1.30, 0.17)		-0.31 (-1.04, 0.43)	
p-value [3]		0.129		0.410	

Brain Fog Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	23	51	43	80	
Mean (StdDev)	2.61 (2.064)	2.79 (2.129)	4.74 (2.962)	4.65 (3.151)	
Median	2.79	2.55	4.36	4.79	
Min, Max	0.0, 7.9	0.0, 8.4	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	23	51	43	80	
LS Mean (StdErr) [2]	-0.54 (0.371)	-0.99 (0.258)	-1.26 (0.329)	-1.70 (0.265)	
95% CI [2]	-1.28, 0.20	-1.51, -0.48	-1.91, -0.61	-2.22, -1.17	
Difference (95% CI) in CFB [2]		-0.45 (-1.27, 0.37)		-0.44 (-1.19, 0.31)	
Hedges'G (95% CI) in CFB		-0.24 (-0.75, 0.25)		-0.19 (-0.57, 0.18)	
p-value [3]		0.275		0.251	
					0.973

Headache Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	26	52	45	87	
Mean (StdDev)	2.15 (1.842)	2.45 (1.929)	5.23 (2.491)	4.96 (2.425)	
Median	1.46	2.50	5.58	4.88	
Min, Max	0.0, 6.9	0.0, 7.2	0.3, 9.9	0.0, 9.9	

Headache Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	26	50	45	85	
Mean (StdDev)	2.10 (1.911)	2.05 (1.780)	4.75 (2.451)	4.28 (2.418)	
Median	1.79	1.70	4.64	4.00	
Min, Max	0.0, 7.0	0.0, 7.5	0.5, 9.1	0.0, 10.0	
C2D1 CFB					
n	26	50	45	85	
LS Mean (StdErr) [2]	-0.05 (0.222)	-0.35 (0.165)	-0.55 (0.215)	-0.77 (0.173)	
95% CI [2]	-0.49, 0.40	-0.68, -0.02	-0.97, -0.12	-1.11, -0.43	
Difference (95% CI) in CFB [2]		-0.31 (-0.79, 0.18)		-0.22 (-0.72, 0.27)	
p-value [3]		0.216		0.372	

Headache Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	26	50	45	83	
Mean (StdDev)	1.80 (1.806)	1.95 (1.718)	4.34 (2.493)	3.84 (2.500)	
Median	1.61	1.69	4.36	3.50	
Min, Max	0.0, 7.1	0.0, 6.1	0.3, 9.1	0.0, 10.0	
C3D1 CFB					
n	26	50	45	83	
LS Mean (StdErr) [2]	-0.51 (0.278)	-0.58 (0.206)	-0.89 (0.279)	-1.14 (0.225)	
95% CI [2]	-1.06, 0.04	-0.99, -0.17	-1.44, -0.34	-1.59, -0.70	
Difference (95% CI) in CFB [2]		-0.07 (-0.68, 0.54)		-0.26 (-0.90, 0.39)	
p-value [3]		0.810		0.433	

Headache Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	24	49	44	84	
Mean (StdDev)	2.15 (1.976)	1.80 (1.687)	4.19 (2.460)	3.67 (2.476)	
Median	2.00	1.44	4.18	3.38	
Min, Max	0.0, 6.8	0.0, 5.7	0.2, 8.4	0.0, 9.9	
C4D1 CFB					
n	24	49	44	84	
LS Mean (StdErr) [2]	-0.08 (0.302)	-0.58 (0.219)	-1.19 (0.310)	-1.53 (0.246)	
95% CI [2]	-0.68, 0.53	-1.02, -0.15	-1.81, -0.58	-2.01, -1.04	
Difference (95% CI) in CFB [2]		-0.50 (-1.17, 0.16)		-0.33 (-1.04, 0.37)	
p-value [3]		0.135		0.351	

Headache Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	51	44	84	
Mean (StdDev)	1.78 (1.558)	1.85 (1.714)	4.27 (2.454)	3.50 (2.519)	
Median	1.64	1.54	4.08	3.21	
Min, Max	0.0, 5.4	0.0, 5.6	0.0, 9.1	0.0, 10.0	
C5D1 CFB					
n	23	51	44	84	
LS Mean (StdErr) [2]	-0.55 (0.307)	-0.64 (0.214)	-1.11 (0.309)	-1.69 (0.245)	
95% CI [2]	-1.16, 0.06	-1.07, -0.22	-1.72, -0.50	-2.18, -1.21	
Difference (95% CI) in CFB [2]		-0.09 (-0.77, 0.58)		-0.58 (-1.29, 0.12)	
p-value [3]		0.785		0.103	

Headache Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	24	52	42	82	
Mean (StdDev)	1.85 (1.668)	1.62 (1.585)	3.87 (2.589)	3.34 (2.624)	
Median	2.21	1.29	3.18	2.79	
Min, Max	0.0, 5.7	0.0, 6.0	0.0, 8.9	0.0, 10.0	
C6D1 CFB					
n	24	52	42	82	
LS Mean (StdErr) [2]	-0.48 (0.274)	-0.97 (0.193)	-1.40 (0.338)	-1.78 (0.265)	
95% CI [2]	-1.03, 0.06	-1.35, -0.58	-2.07, -0.73	-2.31, -1.26	
Difference (95% CI) in CFB [2]		-0.49 (-1.09, 0.12)		-0.38 (-1.15, 0.39)	
p-value [3]		0.112		0.329	

Headache Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	23	51	43	80	
Mean (StdDev)	1.86 (1.667)	1.67 (1.549)	3.95 (2.704)	3.27 (2.606)	
Median	1.57	1.43	3.79	2.96	
Min, Max	0.0, 6.1	0.0, 5.5	0.0, 8.9	0.0, 10.0	
C7D1 CFB					
n	23	51	43	80	
LS Mean (StdErr) [2]	-0.40 (0.318)	-0.90 (0.221)	-1.33 (0.326)	-1.81 (0.263)	
95% CI [2]	-1.04, 0.23	-1.34, -0.46	-1.98, -0.69	-2.33, -1.28	
Difference (95% CI) in CFB [2]		-0.50 (-1.20, 0.20)		-0.47 (-1.22, 0.27)	
Hedges'G (95% CI) in CFB		-0.32 (-0.83, 0.18)		-0.21 (-0.59, 0.17)	
p-value [3]		0.158		0.212	
					0.957

Diarrhea Count					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	26	52	45	87	
Mean (StdDev)	1.01 (0.965)	0.89 (0.709)	1.78 (1.645)	1.77 (1.940)	
Median	0.78	0.82	1.36	1.00	
Min, Max	0.0, 3.8	0.0, 2.6	0.0, 7.2	0.0, 12.2	

Diarrhea Count					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	26	50	45	85	
Mean (StdDev)	0.73 (0.809)	0.58 (0.616)	1.53 (1.406)	1.39 (1.656)	
Median	0.36	0.33	1.00	0.92	
Min, Max	0.0, 2.8	0.0, 2.3	0.0, 4.9	0.0, 10.7	
C2D1 CFB					
n	26	50	45	85	
LS Mean (StdErr) [2]	-0.27 (0.126)	-0.26 (0.093)	-0.37 (0.149)	-0.55 (0.120)	
95% CI [2]	-0.52, -0.02	-0.45, -0.07	-0.66, -0.07	-0.79, -0.32	
Difference (95% CI) in CFB [2]		0.01 (-0.27, 0.28)		-0.19 (-0.53, 0.16)	
p-value [3]		0.967		0.285	

Diarrhea Count					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	26	50	45	83	
Mean (StdDev)	0.72 (0.782)	0.65 (0.699)	1.37 (1.284)	1.18 (1.367)	
Median	0.33	0.37	0.92	0.79	
Min, Max	0.0, 2.3	0.0, 2.5	0.0, 4.4	0.0, 5.8	
C3D1 CFB					
n	26	50	45	83	
LS Mean (StdErr) [2]	-0.33 (0.131)	-0.24 (0.097)	-0.59 (0.203)	-0.84 (0.164)	
95% CI [2]	-0.59, -0.07	-0.43, -0.04	-0.99, -0.19	-1.16, -0.52	
Difference (95% CI) in CFB [2]		0.09 (-0.19, 0.38)		-0.25 (-0.72, 0.21)	
p-value [3]		0.512		0.285	

Diarrhea Count	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	24	49	44	84	
Mean (StdDev)	0.84 (0.960)	0.61 (0.670)	1.27 (1.201)	1.22 (1.611)	
Median	0.46	0.36	0.82	0.63	
Min, Max	0.0, 2.9	0.0, 2.3	0.0, 4.8	0.0, 9.0	
C4D1 CFB					
n	24	49	44	84	
LS Mean (StdErr) [2]	-0.25 (0.142)	-0.27 (0.103)	-0.69 (0.193)	-0.78 (0.153)	
95% CI [2]	-0.53, 0.04	-0.48, -0.06	-1.08, -0.31	-1.09, -0.48	
Difference (95% CI) in CFB [2]		-0.02 (-0.34, 0.29)		-0.09 (-0.53, 0.35)	
p-value [3]		0.888		0.689	

Diarrhea Count	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	51	44	84	
Mean (StdDev)	0.85 (0.950)	0.66 (0.774)	1.29 (1.278)	1.19 (1.704)	
Median	0.43	0.38	0.96	0.63	
Min, Max	0.0, 3.1	0.0, 3.1	0.0, 4.8	0.0, 9.6	
C5D1 CFB					
n	23	51	44	84	
LS Mean (StdErr) [2]	-0.15 (0.157)	-0.22 (0.109)	-0.74 (0.219)	-0.88 (0.174)	
95% CI [2]	-0.47, 0.16	-0.44, -0.00	-1.17, -0.31	-1.22, -0.53	
Difference (95% CI) in CFB [2]		-0.07 (-0.41, 0.28)		-0.14 (-0.64, 0.36)	
p-value [3]		0.699		0.584	

Diarrhea Count	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	24	52	42	82	
Mean (StdDev)	0.73 (0.938)	0.64 (0.745)	1.23 (1.400)	1.11 (1.509)	
Median	0.46	0.39	0.68	0.50	
Min, Max	0.0, 3.9	0.0, 3.3	0.0, 6.5	0.0, 9.0	
C6D1 CFB					
n	24	52	42	82	
LS Mean (StdErr) [2]	-0.32 (0.147)	-0.29 (0.104)	-0.67 (0.190)	-0.86 (0.149)	
95% CI [2]	-0.61, -0.03	-0.50, -0.08	-1.04, -0.29	-1.15, -0.56	
Difference (95% CI) in CFB [2]		0.03 (-0.29, 0.35)		-0.19 (-0.63, 0.24)	
p-value [3]		0.857		0.385	

Diarrhea Count	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	23	51	43	80	
Mean (StdDev)	0.64 (0.657)	0.58 (0.708)	1.27 (1.413)	1.01 (1.272)	
Median	0.43	0.29	0.79	0.31	
Min, Max	0.0, 2.3	0.0, 2.8	0.0, 5.9	0.0, 4.8	
C7D1 CFB					
n	23	51	43	80	
LS Mean (StdErr) [2]	-0.33 (0.136)	-0.30 (0.095)	-0.61 (0.211)	-0.84 (0.170)	
95% CI [2]	-0.60, -0.06	-0.49, -0.11	-1.03, -0.20	-1.18, -0.51	
Difference (95% CI) in CFB [2]		0.03 (-0.27, 0.33)		-0.23 (-0.71, 0.25)	
Hedges'G (95% CI) in CFB		0.04 (-0.46, 0.54)		-0.15 (-0.53, 0.22)	
p-value [3]		0.865		0.351	
					0.443

Diarrhea Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	26	52	45	87	
Mean (StdDev)	1.56 (1.515)	2.02 (1.608)	3.94 (2.721)	3.41 (2.636)	
Median	1.29	1.89	4.00	2.92	
Min, Max	0.0, 5.3	0.0, 7.0	0.0, 9.5	0.0, 9.5	

Diarrhea Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	26	50	45	85	
Mean (StdDev)	1.11 (1.085)	1.46 (1.665)	3.11 (2.628)	2.75 (2.521)	
Median	0.61	1.00	2.64	2.00	
Min, Max	0.0, 3.4	0.0, 6.6	0.0, 9.1	0.0, 8.9	
C2D1 CFB					
n	26	50	45	85	
LS Mean (StdErr) [2]	-0.40 (0.232)	-0.47 (0.172)	-0.76 (0.244)	-0.63 (0.196)	
95% CI [2]	-0.86, 0.07	-0.81, -0.13	-1.25, -0.28	-1.02, -0.24	
Difference (95% CI) in CFB [2]		-0.07 (-0.58, 0.44)		0.13 (-0.43, 0.69)	
p-value [3]		0.777		0.640	

Diarrhea Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	26	50	45	83	
Mean (StdDev)	1.09 (1.111)	1.60 (1.897)	2.91 (2.513)	2.36 (2.353)	
Median	0.70	0.77	2.00	1.69	
Min, Max	0.0, 3.1	0.0, 6.9	0.0, 8.7	0.0, 9.5	
C3D1 CFB					
n	26	50	45	83	
LS Mean (StdErr) [2]	-0.52 (0.249)	-0.41 (0.184)	-1.02 (0.307)	-1.09 (0.248)	
95% CI [2]	-1.01, -0.02	-0.78, -0.04	-1.63, -0.41	-1.58, -0.60	
Difference (95% CI) in CFB [2]		0.11 (-0.44, 0.65)		-0.07 (-0.78, 0.64)	
p-value [3]		0.697		0.841	

Diarrhea Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	24	49	44	84	
Mean (StdDev)	1.29 (1.416)	1.38 (1.536)	3.02 (2.535)	2.37 (2.522)	
Median	0.75	0.82	2.46	1.39	
Min, Max	0.0, 4.6	0.0, 6.6	0.0, 8.3	0.0, 8.9	
C4D1 CFB					
n	24	49	44	84	
LS Mean (StdErr) [2]	-0.32 (0.254)	-0.59 (0.184)	-0.97 (0.302)	-1.11 (0.240)	
95% CI [2]	-0.83, 0.19	-0.96, -0.22	-1.57, -0.37	-1.58, -0.63	
Difference (95% CI) in CFB [2]		-0.27 (-0.83, 0.29)		-0.13 (-0.82, 0.55)	
p-value [3]		0.335		0.700	

Diarrhea Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	51	44	84	
Mean (StdDev)	1.31 (1.312)	1.48 (1.679)	2.95 (2.584)	2.21 (2.423)	
Median	0.79	0.67	2.19	1.33	
Min, Max	0.0, 4.3	0.0, 6.9	0.0, 8.5	0.0, 9.0	
C5D1 CFB					
n	23	51	44	84	
LS Mean (StdErr) [2]	-0.24 (0.284)	-0.50 (0.198)	-1.12 (0.341)	-1.35 (0.270)	
95% CI [2]	-0.80, 0.33	-0.89, -0.10	-1.79, -0.44	-1.89, -0.82	
Difference (95% CI) in CFB [2]		-0.26 (-0.89, 0.36)		-0.24 (-1.01, 0.54)	
p-value [3]		0.403		0.546	

Diarrhea Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	24	52	42	82	
Mean (StdDev)	1.20 (1.304)	1.43 (1.672)	2.75 (2.607)	2.11 (2.407)	
Median	0.86	1.07	2.11	1.27	
Min, Max	0.0, 4.4	0.0, 7.5	0.0, 8.6	0.0, 8.9	
C6D1 CFB					
n	24	52	42	82	
LS Mean (StdErr) [2]	-0.25 (0.267)	-0.59 (0.188)	-1.15 (0.326)	-1.36 (0.256)	
95% CI [2]	-0.79, 0.28	-0.96, -0.21	-1.80, -0.51	-1.86, -0.85	
Difference (95% CI) in CFB [2]		-0.33 (-0.92, 0.25)		-0.20 (-0.95, 0.54)	
p-value [3]		0.261		0.589	

Diarrhea Severity					
	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	23	51	43	80	
Mean (StdDev)	1.09 (1.148)	1.40 (1.539)	2.78 (2.723)	2.06 (2.497)	
Median	0.50	0.64	1.85	0.78	
Min, Max	0.0, 3.4	0.0, 6.6	0.0, 8.6	0.0, 8.7	
C7D1 CFB					
n	23	51	43	80	
LS Mean (StdErr) [2]	-0.29 (0.259)	-0.57 (0.181)	-1.15 (0.357)	-1.39 (0.287)	
95% CI [2]	-0.81, 0.23	-0.93, -0.21	-1.86, -0.45	-1.96, -0.82	
Difference (95% CI) in CFB [2]		-0.28 (-0.85, 0.29)		-0.23 (-1.05, 0.58)	
Hedges'G (95% CI) in CFB		-0.22 (-0.73, 0.28)		-0.09 (-0.47, 0.28)	
p-value [3]		0.332		0.571	
					0.938

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Bone Pain Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	15	28	56	111	
Mean (StdDev)	5.21 (2.765)	4.89 (3.127)	5.45 (2.372)	5.37 (2.448)	
Median	5.36	4.89	5.66	5.64	
Min, Max	0.7, 9.4	0.0, 9.9	0.0, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Bone Pain Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	56	110	
Mean (StdDev)	4.11 (2.371)	4.56 (3.091)	5.00 (2.605)	4.54 (2.613)	
Median	4.14	4.29	5.25	4.07	
Min, Max	0.6, 7.8	0.0, 9.7	0.0, 10.0	0.0, 10.0	
C2D1 CFB					
n	15	27	56	108	
LS Mean (StdErr) [2]	-1.12 (0.304)	-0.46 (0.220)	-0.41 (0.167)	-0.78 (0.122)	
95% CI [2]	-1.73, -0.50	-0.90, -0.01	-0.74, -0.08	-1.02, -0.54	
Difference (95% CI) in CFB [2]		0.66 (-0.08, 1.40)		-0.37 (-0.77, 0.03)	
p-value [3]		0.080		0.073	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Bone Pain Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	27	56	108	
Mean (StdDev)	4.03 (2.574)	4.19 (3.005)	4.84 (2.698)	4.33 (2.695)	
Median	3.82	3.07	5.39	3.93	
Min, Max	0.0, 8.1	0.0, 9.0	0.0, 10.0	0.0, 10.0	
C3D1 CFB					
n	15	27	56	106	
LS Mean (StdErr) [2]	-1.14 (0.379)	-0.81 (0.274)	-0.57 (0.199)	-0.97 (0.147)	
95% CI [2]	-1.90, -0.37	-1.36, -0.25	-0.96, -0.18	-1.26, -0.68	
Difference (95% CI) in CFB [2]		0.33 (-0.60, 1.26)		-0.40 (-0.88, 0.08)	
p-value [3]		0.475		0.104	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Bone Pain Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	14	27	54	108	
Mean (StdDev)	4.41 (2.710)	4.30 (2.995)	4.77 (2.768)	4.28 (2.795)	
Median	4.61	3.54	4.54	3.92	
Min, Max	0.1, 7.7	0.0, 9.0	0.0, 9.8	0.0, 10.0	
C4D1 CFB					
n	14	27	54	106	
LS Mean (StdErr) [2]	-0.64 (0.469)	-0.66 (0.331)	-0.73 (0.236)	-1.04 (0.171)	
95% CI [2]	-1.59, 0.31	-1.33, 0.01	-1.20, -0.27	-1.38, -0.70	
Difference (95% CI) in CFB [2]		-0.01 (-1.16, 1.13)		-0.31 (-0.87, 0.26)	
p-value [3]		0.980		0.288	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Bone Pain Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	28	53	109	
Mean (StdDev)	4.39 (2.442)	4.24 (2.906)	4.78 (2.815)	4.00 (2.820)	
Median	4.39	4.37	4.46	3.50	
Min, Max	0.3, 8.1	0.0, 9.8	0.0, 9.8	0.0, 10.0	
C5D1 CFB					
n	14	28	53	107	
LS Mean (StdErr) [2]	-0.61 (0.434)	-0.58 (0.300)	-0.72 (0.261)	-1.31 (0.186)	
95% CI [2]	-1.49, 0.27	-1.19, 0.02	-1.23, -0.20	-1.67, -0.94	
Difference (95% CI) in CFB [2]		0.03 (-1.02, 1.08)		-0.59 (-1.21, 0.03)	
p-value [3]		0.957		0.063	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Bone Pain Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	28	52	108	
Mean (StdDev)	4.37 (2.575)	4.19 (2.838)	4.73 (2.771)	3.85 (2.733)	
Median	4.43	3.87	4.88	3.63	
Min, Max	0.3, 8.4	0.0, 9.5	0.0, 9.6	0.0, 10.0	
C6D1 CFB					
n	14	28	52	106	
LS Mean (StdErr) [2]	-0.57 (0.487)	-0.62 (0.336)	-0.61 (0.266)	-1.42 (0.188)	
95% CI [2]	-1.55, 0.42	-1.30, 0.06	-1.14, -0.09	-1.79, -1.05	
Difference (95% CI) in CFB [2]		-0.05 (-1.23, 1.13)		-0.81 (-1.44, -0.17)	
p-value [3]		0.928		0.013	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Bone Pain Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	14	27	52	106	
Mean (StdDev)	4.23 (2.668)	3.93 (3.004)	4.71 (2.723)	3.84 (2.730)	
Median	4.21	3.17	5.20	3.39	
Min, Max	0.3, 8.8	0.0, 9.7	0.0, 9.4	0.0, 10.0	
C7D1 CFB					
n	14	27	52	104	
LS Mean (StdErr) [2]	-0.72 (0.550)	-0.77 (0.385)	-0.68 (0.267)	-1.39 (0.191)	
95% CI [2]	-1.83, 0.39	-1.55, 0.00	-1.21, -0.16	-1.77, -1.01	
Difference (95% CI) in CFB [2]		-0.06 (-1.40, 1.29)		-0.71 (-1.34, -0.07)	
Hedges'G (95% CI) in CFB		-0.03 (-0.69, 0.64)		-0.36 (-0.71, -0.03)	
p-value [3]		0.934		0.031	
					0.328

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Abdominal Pain Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	15	28	56	111	
Mean (StdDev)	4.67 (2.460)	3.74 (2.510)	3.80 (2.470)	3.91 (2.219)	
Median	4.50	3.39	3.92	3.86	
Min, Max	0.4, 8.2	0.4, 8.8	0.0, 9.6	0.0, 9.8	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Abdominal Pain Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	56	110	
Mean (StdDev)	3.46 (2.225)	3.37 (2.624)	3.17 (2.221)	3.11 (2.057)	
Median	3.57	2.71	3.11	2.93	
Min, Max	0.2, 7.6	0.1, 9.4	0.0, 8.9	0.0, 8.0	
C2D1 CFB					
n	15	27	56	108	
LS Mean (StdErr) [2]	-1.09 (0.342)	-0.36 (0.248)	-0.58 (0.143)	-0.77 (0.105)	
95% CI [2]	-1.78, -0.40	-0.86, 0.14	-0.87, -0.30	-0.97, -0.56	
Difference (95% CI) in CFB [2]		0.73 (-0.11, 1.57)		-0.18 (-0.53, 0.16)	
p-value [3]		0.085		0.295	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	27	56	108	
Mean (StdDev)	3.07 (1.995)	3.02 (2.430)	3.05 (2.311)	2.71 (2.115)	
Median	2.64	2.36	3.00	2.45	
Min, Max	0.5, 7.2	0.0, 8.3	0.0, 8.4	0.0, 8.3	
C3D1 CFB					
n	15	27	56	106	
LS Mean (StdErr) [2]	-1.43 (0.337)	-0.68 (0.244)	-0.66 (0.194)	-1.09 (0.143)	
95% CI [2]	-2.12, -0.75	-1.18, -0.19	-1.04, -0.28	-1.37, -0.80	
Difference (95% CI) in CFB [2]		0.75 (-0.07, 1.57)		-0.42 (-0.89, 0.04)	
p-value [3]		0.073		0.076	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Abdominal Pain Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	14	27	54	108	
Mean (StdDev)	3.07 (1.959)	2.81 (2.327)	3.00 (2.267)	2.45 (2.148)	
Median	2.89	2.43	3.04	2.04	
Min, Max	0.6, 6.6	0.0, 9.1	0.0, 7.9	0.0, 8.4	
C4D1 CFB					
n	14	27	54	106	
LS Mean (StdErr) [2]	-1.46 (0.410)	-0.86 (0.289)	-0.78 (0.231)	-1.39 (0.167)	
95% CI [2]	-2.29, -0.63	-1.44, -0.27	-1.24, -0.32	-1.72, -1.06	
Difference (95% CI) in CFB [2]		0.61 (-0.39, 1.60)		-0.61 (-1.16, -0.05)	
p-value [3]		0.225		0.032	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	28	53	109	
Mean (StdDev)	2.99 (1.715)	2.79 (2.273)	3.13 (2.337)	2.33 (2.262)	
Median	2.43	2.20	3.00	1.79	
Min, Max	0.7, 5.9	0.0, 7.6	0.0, 8.1	0.0, 9.4	
C5D1 CFB					
n	14	28	53	107	
LS Mean (StdErr) [2]	-1.48 (0.469)	-0.85 (0.324)	-0.66 (0.252)	-1.51 (0.180)	
95% CI [2]	-2.43, -0.53	-1.50, -0.19	-1.16, -0.17	-1.87, -1.16	
Difference (95% CI) in CFB [2]		0.63 (-0.51, 1.77)		-0.85 (-1.45, -0.25)	
p-value [3]		0.269		0.006	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	28	52	108	
Mean (StdDev)	2.78 (1.933)	2.56 (2.474)	2.55 (2.138)	2.20 (2.157)	
Median	2.52	2.20	2.29	1.71	
Min, Max	0.0, 5.8	0.0, 9.6	0.0, 7.1	0.0, 8.9	
C6D1 CFB					
n	14	28	52	106	
LS Mean (StdErr) [2]	-1.69 (0.550)	-1.07 (0.380)	-1.03 (0.249)	-1.58 (0.177)	
95% CI [2]	-2.81, -0.58	-1.84, -0.30	-1.52, -0.54	-1.93, -1.23	
Difference (95% CI) in CFB [2]		0.62 (-0.71, 1.96)		-0.55 (-1.14, 0.05)	
p-value [3]		0.351		0.072	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Abdominal Pain Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	14	27	52	106	
Mean (StdDev)	2.85 (1.738)	2.52 (2.373)	2.75 (2.435)	2.26 (2.144)	
Median	2.60	2.00	2.36	1.85	
Min, Max	0.2, 5.8	0.0, 9.4	0.0, 8.3	0.0, 8.6	
C7D1 CFB					
n	14	27	52	104	
LS Mean (StdErr) [2]	-1.62 (0.509)	-1.05 (0.356)	-0.89 (0.248)	-1.53 (0.177)	
95% CI [2]	-2.65, -0.59	-1.77, -0.32	-1.38, -0.40	-1.88, -1.18	
Difference (95% CI) in CFB [2]		0.58 (-0.67, 1.82)		-0.64 (-1.24, -0.05)	
Hedges'G (95% CI) in CFB		0.30 (-0.35, 0.99)		-0.35 (-0.70, -0.02)	
p-value [3]		0.355		0.034	
					0.053

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Nausea Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	15	28	56	111	
Mean (StdDev)	3.97 (2.727)	3.18 (2.915)	3.20 (2.440)	2.88 (2.456)	
Median	3.91	2.59	2.78	2.38	
Min, Max	0.3, 8.6	0.0, 8.9	0.0, 8.9	0.0, 9.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Nausea Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	56	110	
Mean (StdDev)	2.86 (2.201)	3.23 (2.708)	2.86 (2.428)	2.39 (2.209)	
Median	2.25	2.57	2.52	2.00	
Min, Max	0.2, 7.4	0.0, 8.8	0.0, 8.3	0.0, 8.2	
C2D1 CFB					
n	15	27	56	108	
LS Mean (StdErr) [2]	-0.92 (0.306)	0.05 (0.221)	-0.29 (0.163)	-0.44 (0.119)	
95% CI [2]	-1.54, -0.30	-0.40, 0.50	-0.61, 0.03	-0.67, -0.20	
Difference (95% CI) in CFB [2]		0.97 (0.22, 1.72)		-0.15 (-0.54, 0.24)	
p-value [3]		0.012		0.452	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Nausea Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	27	56	108	
Mean (StdDev)	2.13 (2.111)	2.91 (2.503)	2.63 (2.354)	2.14 (2.162)	
Median	1.54	2.00	2.19	1.55	
Min, Max	0.0, 7.0	0.0, 8.9	0.0, 7.7	0.0, 7.9	
C3D1 CFB					
n	15	27	56	106	
LS Mean (StdErr) [2]	-1.53 (0.340)	-0.22 (0.246)	-0.49 (0.197)	-0.64 (0.145)	
95% CI [2]	-2.21, -0.84	-0.72, 0.28	-0.88, -0.10	-0.93, -0.36	
Difference (95% CI) in CFB [2]		1.31 (0.48, 2.14)		-0.15 (-0.63, 0.32)	
p-value [3]		0.003		0.530	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Nausea Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	14	27	54	108	
Mean (StdDev)	2.02 (1.999)	2.53 (2.486)	2.74 (2.295)	1.88 (2.132)	
Median	1.61	2.00	2.33	1.16	
Min, Max	0.0, 6.6	0.0, 9.2	0.0, 7.4	0.0, 8.4	
C4D1 CFB					
n	14	27	54	106	
LS Mean (StdErr) [2]	-1.74 (0.361)	-0.59 (0.255)	-0.46 (0.226)	-0.93 (0.164)	
95% CI [2]	-2.48, -1.01	-1.10, -0.07	-0.90, -0.01	-1.25, -0.60	
Difference (95% CI) in CFB [2]		1.16 (0.28, 2.03)		-0.47 (-1.01, 0.07)	
p-value [3]		0.011		0.089	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Nausea Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	28	53	109	
Mean (StdDev)	1.97 (1.951)	2.51 (2.371)	2.82 (2.281)	1.86 (2.161)	
Median	1.50	1.82	2.82	1.21	
Min, Max	0.1, 6.1	0.0, 8.4	0.0, 8.5	0.0, 8.9	
C5D1 CFB					
n	14	28	53	107	
LS Mean (StdErr) [2]	-1.70 (0.465)	-0.54 (0.321)	-0.41 (0.239)	-0.94 (0.170)	
95% CI [2]	-2.64, -0.76	-1.19, 0.11	-0.88, 0.06	-1.28, -0.61	
Difference (95% CI) in CFB [2]		1.16 (0.04, 2.29)		-0.53 (-1.10, 0.04)	
p-value [3]		0.043		0.066	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Nausea Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	28	52	108	
Mean (StdDev)	1.68 (2.012)	2.18 (2.459)	2.48 (2.136)	1.68 (2.045)	
Median	0.77	1.52	2.32	0.93	
Min, Max	0.0, 6.4	0.0, 9.9	0.0, 7.9	0.0, 8.9	
C6D1 CFB					
n	14	28	52	106	
LS Mean (StdErr) [2]	-2.02 (0.471)	-0.88 (0.325)	-0.65 (0.239)	-1.05 (0.170)	
95% CI [2]	-2.97, -1.07	-1.54, -0.22	-1.12, -0.18	-1.39, -0.72	
Difference (95% CI) in CFB [2]		1.14 (-0.00, 2.28)		-0.40 (-0.97, 0.17)	
p-value [3]		0.050		0.166	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Nausea Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	14	27	52	106	
Mean (StdDev)	1.95 (1.968)	2.11 (2.323)	2.53 (2.356)	1.76 (2.088)	
Median	1.26	1.67	2.29	1.04	
Min, Max	0.0, 5.9	0.0, 9.5	0.0, 7.7	0.0, 8.3	
C7D1 CFB					
n	14	27	52	104	
LS Mean (StdErr) [2]	-1.71 (0.522)	-0.84 (0.365)	-0.62 (0.259)	-1.00 (0.185)	
95% CI [2]	-2.77, -0.66	-1.58, -0.10	-1.13, -0.11	-1.37, -0.64	
Difference (95% CI) in CFB [2]		0.87 (-0.41, 2.14)		-0.38 (-1.00, 0.23)	
Hedges'G (95% CI) in CFB		0.44 (-0.20, 1.14)		-0.20 (-0.54, 0.13)	
p-value [3]		0.176		0.222	
					0.049

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Spots Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	15	28	56	111	
Mean (StdDev)	5.12 (2.885)	4.98 (3.326)	5.95 (3.201)	5.37 (2.969)	
Median	5.64	4.96	6.48	5.69	
Min, Max	0.0, 8.5	0.0, 10.0	0.0, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Spots Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	56	110	
Mean (StdDev)	4.43 (2.571)	4.30 (2.900)	5.65 (3.014)	4.48 (2.771)	
Median	5.42	4.67	5.86	4.47	
Min, Max	0.0, 6.9	0.0, 10.0	0.0, 10.0	0.0, 9.9	
C2D1 CFB					
n	15	27	56	108	
LS Mean (StdErr) [2]	-0.59 (0.349)	-0.67 (0.253)	-0.25 (0.164)	-0.88 (0.120)	
95% CI [2]	-1.29, 0.12	-1.18, -0.16	-0.58, 0.07	-1.12, -0.65	
Difference (95% CI) in CFB [2]		-0.08 (-0.94, 0.77)		-0.63 (-1.03, -0.23)	
p-value [3]		0.845		0.002	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Spots Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	27	56	108	
Mean (StdDev)	4.31 (2.507)	4.13 (2.777)	5.63 (3.061)	4.02 (2.619)	
Median	4.46	4.46	5.65	3.76	
Min, Max	0.0, 8.7	0.0, 8.9	0.0, 10.0	0.0, 9.8	
C3D1 CFB					
n	15	27	56	106	
LS Mean (StdErr) [2]	-0.67 (0.359)	-0.82 (0.260)	-0.24 (0.209)	-1.33 (0.154)	
95% CI [2]	-1.39, 0.06	-1.35, -0.30	-0.65, 0.17	-1.64, -1.03	
Difference (95% CI) in CFB [2]		-0.15 (-1.03, 0.72)		-1.09 (-1.60, -0.58)	
p-value [3]		0.727		<0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Spots Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	14	27	54	108	
Mean (StdDev)	4.40 (2.609)	4.24 (2.713)	5.47 (3.091)	3.73 (2.613)	
Median	4.79	4.25	5.54	3.43	
Min, Max	0.0, 8.9	0.0, 8.9	0.0, 10.0	0.0, 9.4	
C4D1 CFB					
n	14	27	54	106	
LS Mean (StdErr) [2]	-0.54 (0.372)	-0.71 (0.262)	-0.34 (0.221)	-1.63 (0.160)	
95% CI [2]	-1.30, 0.21	-1.24, -0.18	-0.78, 0.10	-1.95, -1.32	
Difference (95% CI) in CFB [2]		-0.17 (-1.07, 0.73)		-1.29 (-1.82, -0.76)	
p-value [3]		0.706		<0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Spots Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	28	53	109	
Mean (StdDev)	3.95 (2.602)	3.89 (2.775)	5.43 (3.084)	3.58 (2.542)	
Median	4.08	4.00	5.14	3.07	
Min, Max	0.0, 9.0	0.0, 9.9	0.0, 10.0	0.0, 9.3	
C5D1 CFB					
n	14	28	53	107	
LS Mean (StdErr) [2]	-1.02 (0.396)	-1.05 (0.273)	-0.32 (0.240)	-1.73 (0.171)	
95% CI [2]	-1.82, -0.22	-1.60, -0.50	-0.80, 0.15	-2.07, -1.39	
Difference (95% CI) in CFB [2]		-0.03 (-0.99, 0.93)		-1.41 (-1.98, -0.83)	
p-value [3]		0.951		<0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Spots Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	28	52	108	
Mean (StdDev)	3.93 (2.384)	4.16 (2.865)	5.53 (3.132)	3.31 (2.495)	
Median	4.32	4.40	5.26	3.00	
Min, Max	0.0, 8.8	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	14	28	52	106	
LS Mean (StdErr) [2]	-1.13 (0.533)	-0.81 (0.368)	-0.26 (0.266)	-1.97 (0.189)	
95% CI [2]	-2.21, -0.06	-1.55, -0.06	-0.79, 0.26	-2.34, -1.59	
Difference (95% CI) in CFB [2]		0.33 (-0.97, 1.62)		-1.70 (-2.34, -1.07)	
p-value [3]		0.612		<0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Spots Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	14	27	52	106	
Mean (StdDev)	3.81 (2.468)	4.09 (2.983)	5.61 (3.009)	3.32 (2.567)	
Median	4.04	4.57	5.36	3.04	
Min, Max	0.0, 9.4	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	14	27	52	104	
LS Mean (StdErr) [2]	-1.23 (0.572)	-0.95 (0.400)	-0.30 (0.266)	-1.95 (0.190)	
95% CI [2]	-2.38, -0.07	-1.76, -0.14	-0.83, 0.22	-2.32, -1.57	
Difference (95% CI) in CFB [2]		0.28 (-1.12, 1.67)		-1.65 (-2.28, -1.01)	
Hedges'G (95% CI) in CFB		0.13 (-0.53, 0.80)		-0.85 (-1.21, -0.51)	
p-value [3]		0.692		<0.0001	
					0.013

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Itching Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	15	28	56	111	
Mean (StdDev)	5.25 (2.219)	5.55 (2.499)	5.83 (2.930)	5.03 (2.876)	
Median	5.07	5.29	6.28	5.00	
Min, Max	0.9, 7.9	1.3, 10.0	0.0, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Itching Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	56	110	
Mean (StdDev)	4.23 (2.164)	4.41 (2.466)	5.30 (2.927)	4.02 (2.506)	
Median	4.21	4.79	5.77	4.07	
Min, Max	1.3, 7.5	0.0, 9.6	0.0, 10.0	0.0, 9.9	
C2D1 CFB					
n	15	27	56	108	
LS Mean (StdErr) [2]	-0.96 (0.454)	-1.13 (0.329)	-0.49 (0.210)	-1.02 (0.154)	
95% CI [2]	-1.88, -0.05	-1.80, -0.47	-0.91, -0.08	-1.32, -0.71	
Difference (95% CI) in CFB [2]		-0.17 (-1.28, 0.94)		-0.52 (-1.03, -0.02)	
p-value [3]		0.761		0.044	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Itching Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	27	56	108	
Mean (StdDev)	3.94 (2.159)	3.95 (2.549)	5.00 (2.944)	3.38 (2.471)	
Median	4.00	4.42	4.85	3.04	
Min, Max	1.0, 7.0	0.0, 9.7	0.0, 10.0	0.0, 9.1	
C3D1 CFB					
n	15	27	56	106	
LS Mean (StdErr) [2]	-1.23 (0.491)	-1.58 (0.355)	-0.72 (0.265)	-1.56 (0.195)	
95% CI [2]	-2.23, -0.24	-2.30, -0.87	-1.25, -0.20	-1.94, -1.17	
Difference (95% CI) in CFB [2]		-0.35 (-1.55, 0.85)		-0.83 (-1.47, -0.19)	
p-value [3]		0.559		0.011	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Itching Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	14	27	54	108	
Mean (StdDev)	3.73 (2.284)	3.85 (2.597)	4.92 (2.976)	3.13 (2.565)	
Median	4.14	4.27	5.18	2.57	
Min, Max	0.0, 6.8	0.0, 9.3	0.0, 10.0	0.0, 10.0	
C4D1 CFB					
n	14	27	54	106	
LS Mean (StdErr) [2]	-1.48 (0.573)	-1.69 (0.404)	-0.88 (0.310)	-1.89 (0.225)	
95% CI [2]	-2.64, -0.32	-2.50, -0.87	-1.49, -0.27	-2.33, -1.44	
Difference (95% CI) in CFB [2]		-0.20 (-1.60, 1.19)		-1.01 (-1.75, -0.27)	
p-value [3]		0.768		0.008	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Itching Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	28	53	109	
Mean (StdDev)	3.58 (1.988)	3.70 (2.566)	5.08 (2.877)	2.88 (2.498)	
Median	4.14	3.57	5.14	2.69	
Min, Max	0.1, 6.2	0.0, 9.2	0.0, 10.0	0.0, 10.0	
C5D1 CFB					
n	14	28	53	107	
LS Mean (StdErr) [2]	-1.57 (0.619)	-1.80 (0.427)	-0.69 (0.320)	-2.03 (0.228)	
95% CI [2]	-2.82, -0.32	-2.67, -0.94	-1.33, -0.06	-2.48, -1.58	
Difference (95% CI) in CFB [2]		-0.23 (-1.73, 1.27)		-1.34 (-2.10, -0.58)	
p-value [3]		0.755		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Itching Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	28	52	108	
Mean (StdDev)	3.70 (1.935)	3.48 (2.629)	4.98 (2.889)	2.88 (2.497)	
Median	3.68	3.11	5.00	2.44	
Min, Max	0.0, 6.0	0.0, 9.9	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	14	28	52	106	
LS Mean (StdErr) [2]	-1.35 (0.655)	-1.99 (0.452)	-0.78 (0.329)	-2.06 (0.233)	
95% CI [2]	-2.67, -0.02	-2.90, -1.07	-1.43, -0.13	-2.53, -1.60	
Difference (95% CI) in CFB [2]		-0.64 (-2.23, 0.95)		-1.28 (-2.07, -0.50)	
p-value [3]		0.421		0.002	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Itching Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	14	27	52	106	
Mean (StdDev)	3.84 (2.012)	3.36 (2.616)	5.10 (2.748)	2.88 (2.488)	
Median	4.21	2.62	5.14	2.67	
Min, Max	0.0, 6.6	0.0, 9.6	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	14	27	52	104	
LS Mean (StdErr) [2]	-1.21 (0.638)	-2.10 (0.446)	-0.76 (0.343)	-2.05 (0.245)	
95% CI [2]	-2.50, 0.08	-3.00, -1.19	-1.44, -0.09	-2.54, -1.57	
Difference (95% CI) in CFB [2]		-0.89 (-2.45, 0.67)		-1.29 (-2.11, -0.47)	
Hedges'G (95% CI) in CFB		-0.37 (-1.07, 0.28)		-0.51 (-0.86, -0.18)	
p-value [3]		0.255		0.002	
					0.686

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Flushing Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	15	28	56	111	
Mean (StdDev)	5.61 (2.398)	5.32 (2.757)	5.74 (2.744)	5.01 (2.475)	
Median	6.00	5.31	5.57	5.14	
Min, Max	1.0, 9.2	0.0, 9.8	0.0, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Flushing Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	56	110	
Mean (StdDev)	4.85 (2.534)	4.57 (2.676)	5.25 (2.784)	4.34 (2.499)	
Median	4.64	4.58	5.01	4.19	
Min, Max	1.2, 9.0	0.0, 10.0	0.0, 10.0	0.0, 9.9	
C2D1 CFB					
n	15	27	56	108	
LS Mean (StdErr) [2]	-0.74 (0.422)	-0.76 (0.306)	-0.45 (0.194)	-0.66 (0.143)	
95% CI [2]	-1.60, 0.11	-1.38, -0.14	-0.84, -0.07	-0.94, -0.38	
Difference (95% CI) in CFB [2]		-0.02 (-1.05, 1.01)		-0.20 (-0.67, 0.27)	
p-value [3]		0.968		0.396	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Flushing Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	27	56	108	
Mean (StdDev)	4.73 (2.710)	4.24 (2.701)	5.04 (2.929)	3.84 (2.440)	
Median	4.69	4.17	5.29	3.71	
Min, Max	0.9, 9.4	0.2, 10.0	0.0, 10.0	0.0, 10.0	
C3D1 CFB					
n	15	27	56	106	
LS Mean (StdErr) [2]	-0.87 (0.526)	-1.09 (0.381)	-0.62 (0.230)	-1.11 (0.170)	
95% CI [2]	-1.93, 0.20	-1.86, -0.32	-1.07, -0.16	-1.45, -0.78	
Difference (95% CI) in CFB [2]		-0.22 (-1.51, 1.07)		-0.49 (-1.05, 0.06)	
p-value [3]		0.731		0.082	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Flushing Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	14	27	54	108	
Mean (StdDev)	4.75 (2.664)	3.91 (2.690)	5.03 (2.962)	3.66 (2.485)	
Median	3.86	3.54	4.93	3.68	
Min, Max	1.6, 9.4	0.0, 10.0	0.0, 10.0	0.0, 9.9	
C4D1 CFB					
n	14	27	54	106	
LS Mean (StdErr) [2]	-0.71 (0.593)	-1.38 (0.418)	-0.68 (0.268)	-1.33 (0.194)	
95% CI [2]	-1.91, 0.49	-2.22, -0.53	-1.21, -0.15	-1.72, -0.95	
Difference (95% CI) in CFB [2]		-0.67 (-2.11, 0.78)		-0.66 (-1.30, -0.01)	
p-value [3]		0.356		0.045	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Flushing Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	28	53	109	
Mean (StdDev)	4.35 (2.834)	3.68 (2.622)	5.12 (2.953)	3.56 (2.489)	
Median	3.71	3.54	5.00	3.50	
Min, Max	0.3, 9.4	0.0, 9.7	0.0, 10.0	0.0, 9.8	
C5D1 CFB					
n	14	28	53	107	
LS Mean (StdErr) [2]	-1.11 (0.671)	-1.59 (0.463)	-0.56 (0.298)	-1.40 (0.212)	
95% CI [2]	-2.47, 0.25	-2.53, -0.66	-1.15, 0.03	-1.82, -0.98	
Difference (95% CI) in CFB [2]		-0.48 (-2.11, 1.14)		-0.84 (-1.55, -0.13)	
p-value [3]		0.552		0.021	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Flushing Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	28	52	108	
Mean (StdDev)	4.50 (2.490)	3.48 (2.669)	4.93 (3.059)	3.42 (2.499)	
Median	3.79	3.46	5.04	3.22	
Min, Max	0.6, 8.8	0.0, 9.8	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	14	28	52	106	
LS Mean (StdErr) [2]	-0.87 (0.689)	-1.77 (0.475)	-0.80 (0.306)	-1.55 (0.217)	
95% CI [2]	-2.26, 0.53	-2.73, -0.81	-1.40, -0.19	-1.98, -1.12	
Difference (95% CI) in CFB [2]		-0.90 (-2.57, 0.77)		-0.75 (-1.48, -0.02)	
p-value [3]		0.281		0.045	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Flushing Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	14	27	52	106	
Mean (StdDev)	4.73 (2.515)	3.44 (2.568)	4.96 (2.988)	3.21 (2.473)	
Median	4.45	3.64	4.84	2.70	
Min, Max	0.9, 9.4	0.0, 9.6	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	14	27	52	104	
LS Mean (StdErr) [2]	-0.58 (0.713)	-1.76 (0.499)	-0.87 (0.314)	-1.69 (0.224)	
95% CI [2]	-2.02, 0.87	-2.77, -0.75	-1.49, -0.25	-2.13, -1.24	
Difference (95% CI) in CFB [2]		-1.18 (-2.92, 0.56)		-0.82 (-1.57, -0.07)	
Hedges'G (95% CI) in CFB		-0.44 (-1.14, 0.21)		-0.36 (-0.70, -0.02)	
p-value [3]		0.178		0.033	
					0.720

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Fatigue Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	15	28	56	111	
Mean (StdDev)	6.93 (1.980)	6.91 (2.083)	6.66 (2.035)	6.59 (2.133)	
Median	6.54	7.11	6.68	6.86	
Min, Max	3.9, 10.0	1.5, 10.0	0.0, 10.0	0.1, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Fatigue Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	56	110	
Mean (StdDev)	6.31 (2.078)	6.14 (2.404)	6.29 (1.969)	5.92 (2.298)	
Median	6.29	6.57	6.30	6.14	
Min, Max	2.6, 9.8	0.7, 10.0	2.3, 10.0	0.1, 10.0	
C2D1 CFB					
n	15	27	56	108	
LS Mean (StdErr) [2]	-0.62 (0.395)	-0.81 (0.286)	-0.35 (0.154)	-0.65 (0.113)	
95% CI [2]	-1.42, 0.18	-1.39, -0.24	-0.65, -0.04	-0.88, -0.43	
Difference (95% CI) in CFB [2]		-0.19 (-1.16, 0.77)		-0.31 (-0.68, 0.06)	
p-value [3]		0.690		0.104	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Fatigue Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	27	56	108	
Mean (StdDev)	5.82 (2.494)	5.80 (2.462)	5.95 (2.307)	5.49 (2.329)	
Median	5.29	6.00	6.00	5.52	
Min, Max	2.6, 10.0	0.9, 10.0	0.3, 10.0	0.2, 10.0	
C3D1 CFB					
n	15	27	56	106	
LS Mean (StdErr) [2]	-1.17 (0.452)	-1.17 (0.327)	-0.68 (0.205)	-1.03 (0.151)	
95% CI [2]	-2.08, -0.25	-1.83, -0.51	-1.08, -0.27	-1.33, -0.73	
Difference (95% CI) in CFB [2]		-0.01 (-1.11, 1.10)		-0.35 (-0.85, 0.14)	
p-value [3]		0.988		0.161	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Fatigue Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	14	27	54	108	
Mean (StdDev)	5.23 (2.704)	5.52 (2.313)	5.80 (2.379)	5.22 (2.535)	
Median	4.50	5.25	6.04	5.28	
Min, Max	2.1, 9.7	1.8, 10.0	0.2, 10.0	0.0, 10.0	
C4D1 CFB					
n	14	27	54	106	
LS Mean (StdErr) [2]	-1.63 (0.516)	-1.39 (0.364)	-0.79 (0.257)	-1.31 (0.186)	
95% CI [2]	-2.67, -0.58	-2.13, -0.66	-1.29, -0.28	-1.68, -0.94	
Difference (95% CI) in CFB [2]		0.23 (-1.02, 1.49)		-0.52 (-1.14, 0.09)	
p-value [3]		0.709		0.095	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Fatigue Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	28	53	109	
Mean (StdDev)	5.43 (2.540)	5.69 (2.401)	5.60 (2.433)	5.10 (2.486)	
Median	5.07	5.77	5.64	5.29	
Min, Max	2.0, 10.0	0.1, 10.0	0.6, 10.0	0.0, 10.0	
C5D1 CFB					
n	14	28	53	107	
LS Mean (StdErr) [2]	-1.35 (0.564)	-1.17 (0.389)	-1.05 (0.264)	-1.48 (0.188)	
95% CI [2]	-2.49, -0.21	-1.95, -0.38	-1.57, -0.53	-1.85, -1.11	
Difference (95% CI) in CFB [2]		0.18 (-1.18, 1.55)		-0.43 (-1.06, 0.20)	
p-value [3]		0.789		0.182	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Fatigue Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	28	52	108	
Mean (StdDev)	5.24 (2.737)	5.53 (2.531)	5.71 (2.374)	4.88 (2.671)	
Median	4.61	5.08	5.96	5.09	
Min, Max	1.8, 10.0	0.0, 10.0	0.4, 10.0	0.0, 10.0	
C6D1 CFB					
n	14	28	52	106	
LS Mean (StdErr) [2]	-1.61 (0.620)	-1.35 (0.428)	-0.81 (0.285)	-1.59 (0.202)	
95% CI [2]	-2.86, -0.35	-2.21, -0.48	-1.37, -0.25	-1.99, -1.20	
Difference (95% CI) in CFB [2]		0.26 (-1.24, 1.76)		-0.78 (-1.46, -0.10)	
p-value [3]		0.729		0.024	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Fatigue Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	14	27	52	106	
Mean (StdDev)	5.20 (2.804)	5.35 (2.517)	5.69 (2.450)	4.77 (2.595)	
Median	4.89	5.22	5.71	5.04	
Min, Max	1.5, 10.0	0.0, 10.0	0.2, 10.0	0.0, 10.0	
C7D1 CFB					
n	14	27	52	104	
LS Mean (StdErr) [2]	-1.64 (0.669)	-1.47 (0.468)	-0.85 (0.283)	-1.68 (0.202)	
95% CI [2]	-2.99, -0.28	-2.42, -0.52	-1.41, -0.29	-2.08, -1.28	
Difference (95% CI) in CFB [2]		0.16 (-1.47, 1.80)		-0.83 (-1.51, -0.16)	
Hedges'G (95% CI) in CFB		0.07 (-0.60, 0.74)		-0.40 (-0.75, -0.07)	
p-value [3]		0.840		0.016	
					0.219

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Dizziness Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	15	28	56	111	
Mean (StdDev)	3.83 (2.677)	3.82 (3.413)	3.51 (2.804)	3.60 (2.731)	
Median	2.64	3.61	3.04	3.57	
Min, Max	0.0, 8.5	0.0, 10.0	0.0, 9.3	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Dizziness Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	56	110	
Mean (StdDev)	2.91 (2.321)	3.56 (3.066)	3.18 (2.741)	2.98 (2.558)	
Median	2.86	3.07	2.62	2.68	
Min, Max	0.0, 7.4	0.0, 10.0	0.0, 8.7	0.0, 10.0	
C2D1 CFB					
n	15	27	56	108	
LS Mean (StdErr) [2]	-0.71 (0.384)	-0.31 (0.278)	-0.30 (0.176)	-0.60 (0.129)	
95% CI [2]	-1.48, 0.07	-0.88, 0.25	-0.64, 0.05	-0.85, -0.34	
Difference (95% CI) in CFB [2]		0.39 (-0.55, 1.33)		-0.30 (-0.72, 0.13)	
p-value [3]		0.402		0.167	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Dizziness Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	27	56	108	
Mean (StdDev)	2.42 (2.483)	3.29 (3.032)	2.85 (2.595)	2.63 (2.562)	
Median	1.85	2.29	2.18	2.11	
Min, Max	0.0, 7.6	0.0, 10.0	0.0, 8.1	0.0, 10.0	
C3D1 CFB					
n	15	27	56	106	
LS Mean (StdErr) [2]	-1.16 (0.467)	-0.58 (0.338)	-0.58 (0.205)	-0.91 (0.151)	
95% CI [2]	-2.11, -0.22	-1.26, 0.11	-0.98, -0.17	-1.20, -0.61	
Difference (95% CI) in CFB [2]		0.59 (-0.56, 1.73)		-0.33 (-0.82, 0.17)	
p-value [3]		0.305		0.195	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Dizziness Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	14	27	54	108	
Mean (StdDev)	2.43 (2.097)	3.05 (2.970)	3.03 (2.770)	2.58 (2.642)	
Median	1.96	2.71	2.61	1.85	
Min, Max	0.0, 7.4	0.0, 10.0	0.0, 9.9	0.0, 10.0	
C4D1 CFB					
n	14	27	54	106	
LS Mean (StdErr) [2]	-1.17 (0.510)	-0.77 (0.359)	-0.39 (0.252)	-0.96 (0.182)	
95% CI [2]	-2.20, -0.13	-1.49, -0.04	-0.89, 0.11	-1.32, -0.60	
Difference (95% CI) in CFB [2]		0.40 (-0.84, 1.64)		-0.57 (-1.17, 0.03)	
p-value [3]		0.517		0.064	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Dizziness Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	28	53	109	
Mean (StdDev)	2.30 (2.044)	3.08 (2.850)	3.09 (2.715)	2.40 (2.563)	
Median	2.14	2.65	2.38	1.71	
Min, Max	0.0, 6.5	0.0, 9.6	0.0, 9.6	0.0, 10.0	
C5D1 CFB					
n	14	28	53	107	
LS Mean (StdErr) [2]	-1.27 (0.592)	-0.62 (0.408)	-0.32 (0.236)	-1.11 (0.168)	
95% CI [2]	-2.46, -0.07	-1.45, 0.20	-0.79, 0.15	-1.44, -0.78	
Difference (95% CI) in CFB [2]		0.64 (-0.79, 2.07)		-0.79 (-1.35, -0.23)	
p-value [3]		0.371		0.006	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Dizziness Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	28	52	108	
Mean (StdDev)	1.79 (1.943)	2.77 (2.755)	2.94 (2.706)	2.19 (2.450)	
Median	1.25	2.40	2.14	1.29	
Min, Max	0.0, 5.9	0.0, 9.7	0.0, 8.6	0.0, 10.0	
C6D1 CFB					
n	14	28	52	106	
LS Mean (StdErr) [2]	-1.72 (0.610)	-0.92 (0.421)	-0.44 (0.255)	-1.25 (0.181)	
95% CI [2]	-2.95, -0.49	-1.77, -0.06	-0.95, 0.06	-1.61, -0.89	
Difference (95% CI) in CFB [2]		0.80 (-0.67, 2.28)		-0.81 (-1.42, -0.20)	
p-value [3]		0.278		0.010	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Dizziness Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	14	27	52	106	
Mean (StdDev)	2.18 (1.861)	2.51 (2.770)	2.87 (2.809)	2.27 (2.494)	
Median	2.04	1.62	1.82	1.54	
Min, Max	0.0, 5.9	0.0, 9.8	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	14	27	52	104	
LS Mean (StdErr) [2]	-1.33 (0.625)	-1.08 (0.438)	-0.56 (0.269)	-1.17 (0.192)	
95% CI [2]	-2.59, -0.06	-1.97, -0.20	-1.09, -0.02	-1.55, -0.79	
Difference (95% CI) in CFB [2]		0.25 (-1.28, 1.78)		-0.61 (-1.26, 0.03)	
Hedges'G (95% CI) in CFB		0.11 (-0.55, 0.78)		-0.31 (-0.65, 0.02)	
p-value [3]		0.744		0.062	
					0.196

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Brain Fog Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	15	28	56	111	
Mean (StdDev)	5.88 (2.387)	5.63 (2.598)	4.80 (2.807)	5.31 (2.487)	
Median	5.07	5.52	5.08	5.54	
Min, Max	1.6, 10.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Brain Fog Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	56	110	
Mean (StdDev)	5.24 (2.250)	5.06 (2.728)	4.34 (2.749)	4.65 (2.677)	
Median	4.14	4.93	4.23	4.54	
Min, Max	2.4, 10.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C2D1 CFB					
n	15	27	56	108	
LS Mean (StdErr) [2]	-0.63 (0.374)	-0.64 (0.270)	-0.43 (0.147)	-0.63 (0.108)	
95% CI [2]	-1.39, 0.12	-1.19, -0.10	-0.72, -0.14	-0.85, -0.42	
Difference (95% CI) in CFB [2]		-0.01 (-0.93, 0.90)		-0.21 (-0.56, 0.15)	
p-value [3]		0.979		0.249	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Brain Fog Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	27	56	108	
Mean (StdDev)	4.95 (2.668)	4.74 (2.937)	4.14 (2.739)	4.33 (2.674)	
Median	3.86	4.43	4.04	4.14	
Min, Max	1.2, 10.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C3D1 CFB					
n	15	27	56	106	
LS Mean (StdErr) [2]	-1.00 (0.439)	-0.99 (0.318)	-0.62 (0.176)	-0.96 (0.130)	
95% CI [2]	-1.89, -0.11	-1.64, -0.35	-0.96, -0.27	-1.22, -0.71	
Difference (95% CI) in CFB [2]		0.01 (-1.07, 1.08)		-0.34 (-0.77, 0.08)	
p-value [3]		0.989		0.112	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Brain Fog Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	14	27	54	108	
Mean (StdDev)	4.41 (2.468)	4.57 (2.947)	4.02 (2.885)	4.08 (2.813)	
Median	3.85	4.36	4.21	3.64	
Min, Max	1.3, 9.6	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C4D1 CFB					
n	14	27	54	106	
LS Mean (StdErr) [2]	-1.35 (0.543)	-1.12 (0.383)	-0.75 (0.221)	-1.17 (0.160)	
95% CI [2]	-2.45, -0.25	-1.90, -0.35	-1.19, -0.32	-1.49, -0.86	
Difference (95% CI) in CFB [2]		0.22 (-1.10, 1.54)		-0.42 (-0.95, 0.11)	
p-value [3]		0.733		0.118	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Brain Fog Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	28	53	109	
Mean (StdDev)	4.46 (2.387)	4.73 (2.885)	3.77 (2.887)	4.02 (2.838)	
Median	3.46	4.70	3.50	4.00	
Min, Max	2.1, 10.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C5D1 CFB					
n	14	28	53	107	
LS Mean (StdErr) [2]	-1.25 (0.594)	-0.88 (0.410)	-0.98 (0.241)	-1.24 (0.172)	
95% CI [2]	-2.45, -0.05	-1.71, -0.05	-1.46, -0.51	-1.58, -0.91	
Difference (95% CI) in CFB [2]		0.37 (-1.07, 1.81)		-0.26 (-0.83, 0.31)	
p-value [3]		0.604		0.372	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Brain Fog Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	28	52	108	
Mean (StdDev)	4.06 (2.443)	4.57 (2.845)	3.95 (2.860)	3.85 (2.889)	
Median	3.75	4.49	3.64	3.23	
Min, Max	0.9, 10.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	14	28	52	106	
LS Mean (StdErr) [2]	-1.59 (0.615)	-1.02 (0.424)	-0.67 (0.231)	-1.33 (0.164)	
95% CI [2]	-2.83, -0.34	-1.88, -0.17	-1.13, -0.21	-1.65, -1.00	
Difference (95% CI) in CFB [2]		0.56 (-0.93, 2.05)		-0.66 (-1.21, -0.11)	
p-value [3]		0.451		0.020	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Brain Fog Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	14	27	52	106	
Mean (StdDev)	4.09 (2.730)	4.43 (2.900)	3.98 (2.916)	3.80 (2.929)	
Median	3.75	4.50	3.51	3.50	
Min, Max	0.8, 10.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	14	27	52	104	
LS Mean (StdErr) [2]	-1.60 (0.668)	-1.10 (0.468)	-0.68 (0.238)	-1.36 (0.170)	
95% CI [2]	-2.95, -0.25	-2.05, -0.15	-1.15, -0.21	-1.70, -1.03	
Difference (95% CI) in CFB [2]		0.50 (-1.13, 2.13)		-0.69 (-1.26, -0.12)	
Hedges'G (95% CI) in CFB		0.20 (-0.46, 0.88)		-0.40 (-0.74, -0.06)	
p-value [3]		0.539		0.018	
					0.105

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Headache Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	15	28	56	111	
Mean (StdDev)	4.71 (2.856)	4.34 (2.622)	3.94 (2.673)	3.94 (2.544)	
Median	4.93	4.18	4.25	3.71	
Min, Max	0.4, 8.9	0.2, 8.7	0.0, 9.9	0.0, 9.9	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Headache Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	56	110	
Mean (StdDev)	4.09 (2.597)	3.75 (2.437)	3.69 (2.610)	3.40 (2.439)	
Median	3.33	3.50	3.75	3.21	
Min, Max	1.1, 8.1	0.2, 8.6	0.0, 9.1	0.0, 10.0	
C2D1 CFB					
n	15	27	56	108	
LS Mean (StdErr) [2]	-0.49 (0.387)	-0.56 (0.280)	-0.21 (0.159)	-0.51 (0.117)	
95% CI [2]	-1.27, 0.29	-1.12, 0.01	-0.53, 0.10	-0.74, -0.28	
Difference (95% CI) in CFB [2]		-0.07 (-1.01, 0.88)		-0.30 (-0.69, 0.08)	
p-value [3]		0.885		0.124	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Headache Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	27	56	108	
Mean (StdDev)	3.47 (2.740)	3.56 (2.451)	3.39 (2.544)	3.05 (2.387)	
Median	2.27	2.79	3.11	2.59	
Min, Max	0.4, 8.0	0.0, 7.7	0.0, 9.1	0.0, 10.0	
C3D1 CFB					
n	15	27	56	106	
LS Mean (StdErr) [2]	-1.19 (0.445)	-0.78 (0.322)	-0.47 (0.211)	-0.81 (0.156)	
95% CI [2]	-2.09, -0.29	-1.43, -0.13	-0.88, -0.05	-1.12, -0.50	
Difference (95% CI) in CFB [2]		0.41 (-0.68, 1.50)		-0.34 (-0.85, 0.17)	
p-value [3]		0.452		0.187	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Headache Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	14	27	54	108	
Mean (StdDev)	3.23 (2.915)	3.10 (2.234)	3.53 (2.392)	2.97 (2.421)	
Median	2.63	3.23	3.32	2.43	
Min, Max	0.0, 8.4	0.0, 7.7	0.0, 8.2	0.0, 9.9	
C4D1 CFB					
n	14	27	54	106	
LS Mean (StdErr) [2]	-1.09 (0.519)	-1.15 (0.366)	-0.39 (0.232)	-0.87 (0.168)	
95% CI [2]	-2.14, -0.04	-1.89, -0.41	-0.85, 0.07	-1.20, -0.53	
Difference (95% CI) in CFB [2]		-0.05 (-1.31, 1.21)		-0.48 (-1.04, 0.08)	
p-value [3]		0.931		0.090	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Headache Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	28	53	109	
Mean (StdDev)	3.12 (2.547)	2.98 (2.210)	3.50 (2.482)	2.88 (2.419)	
Median	2.32	3.40	3.29	2.21	
Min, Max	0.0, 8.1	0.0, 7.9	0.0, 9.1	0.0, 10.0	
C5D1 CFB					
n	14	28	53	107	
LS Mean (StdErr) [2]	-1.23 (0.478)	-1.29 (0.330)	-0.49 (0.240)	-0.99 (0.171)	
95% CI [2]	-2.20, -0.26	-1.95, -0.62	-0.97, -0.02	-1.33, -0.66	
Difference (95% CI) in CFB [2]		-0.05 (-1.21, 1.10)		-0.50 (-1.07, 0.07)	
p-value [3]		0.924		0.085	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Headache Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	28	52	108	
Mean (StdDev)	2.71 (2.508)	2.89 (2.557)	3.25 (2.489)	2.62 (2.374)	
Median	2.45	2.15	2.82	1.89	
Min, Max	0.1, 7.6	0.0, 10.0	0.0, 8.9	0.0, 10.0	
C6D1 CFB					
n	14	28	52	106	
LS Mean (StdErr) [2]	-1.70 (0.563)	-1.40 (0.388)	-0.57 (0.238)	-1.18 (0.169)	
95% CI [2]	-2.84, -0.56	-2.18, -0.61	-1.04, -0.10	-1.51, -0.85	
Difference (95% CI) in CFB [2]		0.31 (-1.06, 1.67)		-0.61 (-1.18, -0.04)	
p-value [3]		0.653		0.036	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Headache Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	14	27	52	106	
Mean (StdDev)	2.91 (2.522)	2.82 (2.441)	3.30 (2.617)	2.61 (2.355)	
Median	2.11	1.92	2.68	2.04	
Min, Max	0.0, 7.5	0.0, 9.6	0.0, 8.9	0.0, 10.0	
C7D1 CFB					
n	14	27	52	104	
LS Mean (StdErr) [2]	-1.51 (0.567)	-1.35 (0.397)	-0.55 (0.241)	-1.20 (0.172)	
95% CI [2]	-2.66, -0.36	-2.15, -0.55	-1.03, -0.08	-1.54, -0.86	
Difference (95% CI) in CFB [2]		0.16 (-1.22, 1.55)		-0.65 (-1.23, -0.08)	
Hedges'G (95% CI) in CFB		0.08 (-0.59, 0.75)		-0.37 (-0.71, -0.04)	
p-value [3]		0.815		0.027	
					0.243

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Count

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	15	28	56	111	
Mean (StdDev)	2.22 (2.230)	1.91 (2.623)	1.30 (1.149)	1.32 (1.280)	
Median	1.29	1.04	1.04	0.93	
Min, Max	0.2, 7.2	0.0, 12.2	0.0, 4.0	0.0, 5.4	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Count

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	56	110	
Mean (StdDev)	1.26 (1.531)	1.58 (2.158)	1.23 (1.214)	0.98 (1.144)	
Median	0.50	1.21	0.68	0.61	
Min, Max	0.0, 4.5	0.0, 10.7	0.0, 4.9	0.0, 5.1	
C2D1 CFB					
n	15	27	56	108	
LS Mean (StdErr) [2]	-0.87 (0.342)	-0.27 (0.248)	-0.08 (0.087)	-0.38 (0.064)	
95% CI [2]	-1.56, -0.18	-0.77, 0.23	-0.25, 0.09	-0.50, -0.25	
Difference (95% CI) in CFB [2]		0.60 (-0.24, 1.44)		-0.30 (-0.51, -0.09)	
p-value [3]		0.156		0.005	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Count

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	27	56	108	
Mean (StdDev)	1.14 (1.394)	1.21 (1.577)	1.13 (1.109)	0.93 (1.062)	
Median	0.50	0.85	0.70	0.57	
Min, Max	0.0, 3.9	0.0, 5.8	0.0, 4.4	0.0, 4.4	
C3D1 CFB					
n	15	27	56	106	
LS Mean (StdErr) [2]	-0.91 (0.458)	-0.61 (0.332)	-0.15 (0.115)	-0.39 (0.085)	
95% CI [2]	-1.84, 0.02	-1.28, 0.06	-0.38, 0.08	-0.55, -0.22	
Difference (95% CI) in CFB [2]		0.30 (-0.82, 1.42)		-0.24 (-0.51, 0.04)	
p-value [3]		0.585		0.095	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Count

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	14	27	54	108	
Mean (StdDev)	1.19 (1.484)	1.26 (1.858)	1.10 (1.040)	0.92 (1.213)	
Median	0.50	0.57	0.76	0.46	
Min, Max	0.0, 4.8	0.0, 9.0	0.0, 4.3	0.0, 6.2	
C4D1 CFB					
n	14	27	54	106	
LS Mean (StdErr) [2]	-0.97 (0.421)	-0.56 (0.297)	-0.19 (0.118)	-0.38 (0.085)	
95% CI [2]	-1.83, -0.12	-1.17, 0.04	-0.43, 0.04	-0.55, -0.21	
Difference (95% CI) in CFB [2]		0.41 (-0.61, 1.43)		-0.19 (-0.47, 0.10)	
p-value [3]		0.424		0.196	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Count

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	28	53	109	
Mean (StdDev)	1.24 (1.440)	1.18 (1.870)	1.11 (1.126)	0.95 (1.307)	
Median	0.50	0.59	0.77	0.46	
Min, Max	0.0, 4.8	0.0, 9.6	0.0, 4.0	0.0, 8.1	
C5D1 CFB					
n	14	28	53	107	
LS Mean (StdErr) [2]	-0.85 (0.408)	-0.66 (0.282)	-0.18 (0.147)	-0.37 (0.105)	
95% CI [2]	-1.67, -0.02	-1.23, -0.09	-0.47, 0.11	-0.58, -0.16	
Difference (95% CI) in CFB [2]		0.18 (-0.81, 1.17)		-0.19 (-0.54, 0.16)	
p-value [3]		0.712		0.288	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Count

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	28	52	108	
Mean (StdDev)	1.26 (1.819)	1.20 (1.816)	0.99 (1.091)	0.84 (1.101)	
Median	0.64	0.48	0.64	0.43	
Min, Max	0.0, 6.5	0.0, 9.0	0.0, 4.3	0.0, 5.3	
C6D1 CFB					
n	14	28	52	106	
LS Mean (StdErr) [2]	-0.90 (0.403)	-0.66 (0.278)	-0.22 (0.117)	-0.42 (0.083)	
95% CI [2]	-1.71, -0.08	-1.22, -0.10	-0.45, 0.01	-0.59, -0.26	
Difference (95% CI) in CFB [2]		0.24 (-0.74, 1.21)		-0.20 (-0.48, 0.08)	
p-value [3]		0.625		0.160	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Count

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	14	27	52	106	
Mean (StdDev)	1.32 (1.615)	0.97 (1.126)	0.97 (1.121)	0.79 (1.097)	
Median	0.57	0.42	0.46	0.25	
Min, Max	0.0, 5.9	0.0, 3.4	0.0, 4.1	0.0, 4.8	
C7D1 CFB					
n	14	27	52	104	
LS Mean (StdErr) [2]	-0.86 (0.410)	-0.53 (0.287)	-0.26 (0.133)	-0.52 (0.095)	
95% CI [2]	-1.69, -0.03	-1.11, 0.06	-0.53, 0.00	-0.71, -0.33	
Difference (95% CI) in CFB [2]		0.33 (-0.67, 1.34)		-0.26 (-0.58, 0.06)	
Hedges'G (95% CI) in CFB		0.22 (-0.44, 0.90)		-0.27 (-0.61, 0.07)	
p-value [3]		0.505		0.111	
					0.112

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	15	28	56	111	
Mean (StdDev)	3.57 (2.480)	2.87 (2.710)	2.93 (2.647)	2.90 (2.324)	
Median	2.79	1.82	1.89	2.50	
Min, Max	0.6, 8.1	0.0, 9.5	0.0, 9.5	0.0, 9.4	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	56	110	
Mean (StdDev)	2.14 (2.358)	2.90 (2.643)	2.44 (2.414)	2.15 (2.243)	
Median	1.36	2.00	1.85	1.30	
Min, Max	0.0, 7.3	0.0, 7.1	0.0, 9.1	0.0, 8.9	
C2D1 CFB					
n	15	27	56	108	
LS Mean (StdErr) [2]	-1.43 (0.423)	0.04 (0.306)	-0.47 (0.171)	-0.77 (0.125)	
95% CI [2]	-2.29, -0.58	-0.58, 0.65	-0.81, -0.13	-1.02, -0.52	
Difference (95% CI) in CFB [2]		1.47 (0.43, 2.50)		-0.30 (-0.72, 0.11)	
p-value [3]		0.007		0.147	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	27	56	108	
Mean (StdDev)	2.04 (2.423)	2.39 (2.646)	2.30 (2.259)	2.02 (2.131)	
Median	0.86	1.07	1.50	1.18	
Min, Max	0.0, 7.4	0.0, 9.5	0.0, 8.7	0.0, 8.1	
C3D1 CFB					
n	15	27	56	106	
LS Mean (StdErr) [2]	-1.43 (0.502)	-0.43 (0.364)	-0.56 (0.217)	-0.83 (0.160)	
95% CI [2]	-2.45, -0.42	-1.16, 0.31	-0.99, -0.14	-1.15, -0.52	
Difference (95% CI) in CFB [2]		1.00 (-0.22, 2.23)		-0.27 (-0.79, 0.26)	
p-value [3]		0.106		0.318	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Severity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	14	27	54	108	
Mean (StdDev)	2.17 (2.346)	2.33 (2.452)	2.47 (2.366)	1.94 (2.221)	
Median	1.26	1.18	1.84	0.96	
Min, Max	0.0, 6.5	0.0, 7.5	0.0, 8.3	0.0, 8.9	
C4D1 CFB					
n	14	27	54	106	
LS Mean (StdErr) [2]	-1.48 (0.478)	-0.50 (0.337)	-0.43 (0.218)	-0.91 (0.158)	
95% CI [2]	-2.45, -0.51	-1.18, 0.18	-0.86, 0.00	-1.22, -0.60	
Difference (95% CI) in CFB [2]		0.98 (-0.19, 2.14)		-0.48 (-1.00, 0.04)	
p-value [3]		0.097		0.073	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	28	53	109	
Mean (StdDev)	2.10 (2.050)	2.16 (2.315)	2.47 (2.440)	1.90 (2.180)	
Median	1.14	1.34	1.93	1.07	
Min, Max	0.0, 6.2	0.0, 7.9	0.0, 8.5	0.0, 9.0	
C5D1 CFB					
n	14	28	53	107	
LS Mean (StdErr) [2]	-1.43 (0.560)	-0.65 (0.386)	-0.45 (0.245)	-0.96 (0.175)	
95% CI [2]	-2.57, -0.30	-1.43, 0.14	-0.94, 0.03	-1.31, -0.62	
Difference (95% CI) in CFB [2]		0.79 (-0.57, 2.15)		-0.51 (-1.10, 0.07)	
p-value [3]		0.247		0.085	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	28	52	108	
Mean (StdDev)	2.09 (2.231)	2.18 (2.453)	2.21 (2.385)	1.72 (2.087)	
Median	1.57	1.11	1.32	1.07	
Min, Max	0.0, 6.8	0.0, 8.9	0.0, 8.6	0.0, 8.6	
C6D1 CFB					
n	14	28	52	106	
LS Mean (StdErr) [2]	-1.48 (0.552)	-0.64 (0.380)	-0.51 (0.227)	-1.05 (0.161)	
95% CI [2]	-2.60, -0.37	-1.41, 0.13	-0.95, -0.06	-1.36, -0.73	
Difference (95% CI) in CFB [2]		0.84 (-0.49, 2.18)		-0.54 (-1.08, 0.00)	
p-value [3]		0.209		0.051	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.6a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Severity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	14	27	52	106	
Mean (StdDev)	2.14 (2.012)	2.17 (2.484)	2.20 (2.546)	1.67 (2.105)	
Median	1.85	0.71	1.15	0.68	
Min, Max	0.0, 6.3	0.0, 8.7	0.0, 8.6	0.0, 8.4	
C7D1 CFB					
n	14	27	52	104	
LS Mean (StdErr) [2]	-1.45 (0.600)	-0.54 (0.420)	-0.59 (0.245)	-1.14 (0.175)	
95% CI [2]	-2.66, -0.24	-1.39, 0.31	-1.07, -0.10	-1.49, -0.79	
Difference (95% CI) in CFB [2]		0.91 (-0.55, 2.38)		-0.55 (-1.14, 0.03)	
Hedges'G (95% CI) in CFB		0.41 (-0.24, 1.10)		-0.31 (-0.65, 0.02)	
p-value [3]		0.216		0.064	
					0.036

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 14:58/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Bone Pain Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	67	129	4	10	
Mean (StdDev)	5.37 (2.481)	5.10 (2.554)	5.95 (1.817)	7.42 (2.197)	
Median	5.58	5.29	5.89	7.39	
Min, Max	0.0, 10.0	0.0, 10.0	4.1, 7.9	3.7, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Bone Pain Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	67	127	4	10	
Mean (StdDev)	4.74 (2.589)	4.39 (2.616)	6.09 (2.011)	6.47 (3.169)	
Median	4.85	4.00	6.00	7.11	
Min, Max	0.0, 10.0	0.0, 9.9	4.3, 8.1	1.7, 10.0	
C2D1 CFB					
n	67	125	4	10	
LS Mean (StdErr) [2]	-0.58 (0.164)	-0.70 (0.129)	0.58 (0.982)	-0.57 (0.752)	
95% CI [2]	-0.91, -0.26	-0.95, -0.44	-1.61, 2.77	-2.25, 1.10	
Difference (95% CI) in CFB [2]		-0.11 (-0.48, 0.25)		-1.15 (-2.97, 0.67)	
p-value [3]		0.546		0.189	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Bone Pain Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	67	125	4	10	
Mean (StdDev)	4.58 (2.695)	4.07 (2.635)	6.16 (2.003)	7.18 (2.633)	
Median	4.77	3.57	6.46	7.65	
Min, Max	0.0, 10.0	0.0, 10.0	3.6, 8.1	1.6, 10.0	
C3D1 CFB					
n	67	123	4	10	
LS Mean (StdErr) [2]	-0.72 (0.195)	-0.99 (0.154)	-0.30 (0.902)	-0.81 (0.690)	
95% CI [2]	-1.11, -0.34	-1.29, -0.68	-2.30, 1.71	-2.35, 0.73	
Difference (95% CI) in CFB [2]		-0.26 (-0.70, 0.18)		-0.51 (-2.18, 1.16)	
p-value [3]		0.239		0.509	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Bone Pain Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	64	125	4	10	
Mean (StdDev)	4.67 (2.758)	4.04 (2.704)	5.04 (2.770)	7.34 (2.623)	
Median	4.54	3.50	5.25	7.95	
Min, Max	0.0, 9.8	0.0, 10.0	2.1, 7.6	2.1, 10.0	
C4D1 CFB					
n	64	123	4	10	
LS Mean (StdErr) [2]	-0.61 (0.235)	-0.94 (0.181)	-1.58 (1.000)	-0.72 (0.766)	
95% CI [2]	-1.07, -0.15	-1.30, -0.58	-3.80, 0.65	-2.42, 0.99	
Difference (95% CI) in CFB [2]		-0.33 (-0.85, 0.19)		0.86 (-0.99, 2.71)	
p-value [3]		0.216		0.325	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Bone Pain Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	63	127	4	10	
Mean (StdDev)	4.67 (2.772)	3.80 (2.664)	5.10 (2.191)	7.24 (3.066)	
Median	4.46	3.38	4.75	7.96	
Min, Max	0.0, 9.8	0.0, 10.0	3.2, 7.7	1.8, 10.0	
C5D1 CFB					
n	63	125	4	10	
LS Mean (StdErr) [2]	-0.54 (0.250)	-1.08 (0.189)	-0.94 (1.263)	-0.40 (0.967)	
95% CI [2]	-1.03, -0.04	-1.45, -0.71	-3.75, 1.88	-2.56, 1.75	
Difference (95% CI) in CFB [2]		-0.55 (-1.10, 0.01)		0.53 (-1.80, 2.87)	
p-value [3]		0.054		0.622	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Bone Pain Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	62	126	4	10	
Mean (StdDev)	4.60 (2.733)	3.69 (2.586)	5.55 (2.584)	6.80 (3.223)	
Median	4.88	3.42	5.32	8.03	
Min, Max	0.0, 9.6	0.0, 10.0	3.0, 8.6	1.4, 10.0	
C6D1 CFB					
n	62	124	4	10	
LS Mean (StdErr) [2]	-0.47 (0.259)	-1.15 (0.196)	-0.42 (1.203)	-0.80 (0.921)	
95% CI [2]	-0.98, 0.05	-1.53, -0.76	-3.10, 2.26	-2.85, 1.25	
Difference (95% CI) in CFB [2]		-0.68 (-1.26, -0.10)		-0.39 (-2.61, 1.84)	
p-value [3]		0.021		0.708	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Bone Pain Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	63	123	3	10	
Mean (StdDev)	4.56 (2.718)	3.63 (2.597)	5.74 (2.374)	6.66 (3.499)	
Median	4.93	3.36	7.00	7.86	
Min, Max	0.0, 9.4	0.0, 10.0	3.0, 7.2	1.0, 10.0	
C7D1 CFB					
n	63	121	3	10	
LS Mean (StdErr) [2]	-0.58 (0.264)	-1.20 (0.202)	-0.64 (1.575)	-0.63 (1.102)	
95% CI [2]	-1.10, -0.06	-1.60, -0.80	-4.21, 2.92	-3.13, 1.86	
Difference (95% CI) in CFB [2]		-0.62 (-1.21, -0.03)		0.01 (-2.93, 2.95)	
Hedges'G (95% CI) in CFB		-0.28 (-0.59, 0.02)		0.00 (-1.45, 1.45)	
p-value [3]		0.040		0.993	
					0.603

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Abdominal Pain Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	67	129	4	10	
Mean (StdDev)	3.93 (2.477)	3.81 (2.252)	4.84 (2.663)	4.68 (2.503)	
Median	4.07	3.64	3.96	4.74	
Min, Max	0.0, 9.6	0.0, 9.8	2.7, 8.7	1.0, 9.6	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Abdominal Pain Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	67	127	4	10	
Mean (StdDev)	3.16 (2.240)	3.11 (2.163)	4.41 (1.240)	3.82 (2.296)	
Median	3.08	2.79	4.25	3.54	
Min, Max	0.0, 8.9	0.0, 9.4	3.1, 6.0	0.3, 7.9	
C2D1 CFB					
n	67	125	4	10	
LS Mean (StdErr) [2]	-0.69 (0.148)	-0.66 (0.117)	0.12 (0.987)	-0.31 (0.756)	
95% CI [2]	-0.98, -0.40	-0.89, -0.43	-2.08, 2.32	-1.99, 1.37	
Difference (95% CI) in CFB [2]		0.03 (-0.30, 0.36)		-0.43 (-2.25, 1.40)	
p-value [3]		0.862		0.614	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Abdominal Pain Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	67	125	4	10	
Mean (StdDev)	2.98 (2.264)	2.72 (2.119)	4.36 (1.126)	3.42 (2.846)	
Median	2.64	2.36	4.32	4.22	
Min, Max	0.0, 8.4	0.0, 8.3	3.3, 5.5	0.0, 8.3	
C3D1 CFB					
n	67	123	4	10	
LS Mean (StdErr) [2]	-0.84 (0.189)	-1.00 (0.149)	0.39 (1.088)	-0.50 (0.833)	
95% CI [2]	-1.21, -0.47	-1.29, -0.71	-2.03, 2.82	-2.36, 1.35	
Difference (95% CI) in CFB [2]		-0.16 (-0.58, 0.27)		-0.89 (-2.91, 1.12)	
p-value [3]		0.462		0.346	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Abdominal Pain Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	64	125	4	10	
Mean (StdDev)	2.94 (2.226)	2.47 (2.133)	4.30 (1.009)	3.17 (2.762)	
Median	2.96	2.07	4.14	3.93	
Min, Max	0.0, 7.9	0.0, 9.1	3.4, 5.6	0.0, 8.4	
C4D1 CFB					
n	64	123	4	10	
LS Mean (StdErr) [2]	-0.94 (0.227)	-1.26 (0.175)	0.09 (1.283)	-0.90 (0.982)	
95% CI [2]	-1.39, -0.49	-1.60, -0.91	-2.77, 2.95	-3.09, 1.29	
Difference (95% CI) in CFB [2]		-0.32 (-0.82, 0.19)		-0.99 (-3.36, 1.38)	
p-value [3]		0.216		0.375	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Abdominal Pain Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	63	127	4	10	
Mean (StdDev)	3.04 (2.251)	2.29 (2.062)	4.12 (1.133)	4.20 (3.759)	
Median	2.85	1.85	4.59	3.82	
Min, Max	0.0, 8.1	0.0, 8.0	2.4, 4.9	0.0, 9.4	
C5D1 CFB					
n	63	125	4	10	
LS Mean (StdErr) [2]	-0.82 (0.240)	-1.43 (0.181)	1.23 (1.721)	1.09 (1.318)	
95% CI [2]	-1.30, -0.35	-1.79, -1.08	-2.60, 5.07	-1.85, 4.02	
Difference (95% CI) in CFB [2]		-0.61 (-1.14, -0.08)		-0.14 (-3.33, 3.04)	
p-value [3]		0.025		0.922	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Abdominal Pain Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	62	126	4	10	
Mean (StdDev)	2.50 (2.107)	2.17 (2.137)	4.11 (0.792)	3.54 (2.944)	
Median	2.22	1.71	3.96	3.18	
Min, Max	0.0, 7.1	0.0, 9.6	3.4, 5.1	0.0, 8.9	
C6D1 CFB					
n	62	124	4	10	
LS Mean (StdErr) [2]	-1.19 (0.253)	-1.50 (0.191)	1.08 (1.211)	0.52 (0.927)	
95% CI [2]	-1.69, -0.69	-1.88, -1.13	-1.62, 3.78	-1.54, 2.59	
Difference (95% CI) in CFB [2]		-0.31 (-0.87, 0.25)		-0.56 (-2.80, 1.69)	
p-value [3]		0.280		0.593	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Abdominal Pain Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	63	123	3	10	
Mean (StdDev)	2.71 (2.317)	2.27 (2.139)	4.05 (1.358)	2.89 (2.765)	
Median	2.29	1.82	4.00	2.29	
Min, Max	0.0, 8.3	0.0, 9.4	2.7, 5.4	0.0, 8.4	
C7D1 CFB					
n	63	121	3	10	
LS Mean (StdErr) [2]	-1.09 (0.247)	-1.43 (0.190)	1.06 (1.320)	-0.05 (0.924)	
95% CI [2]	-1.57, -0.60	-1.81, -1.06	-1.93, 4.04	-2.14, 2.04	
Difference (95% CI) in CFB [2]		-0.35 (-0.90, 0.20)		-1.10 (-3.57, 1.36)	
Hedges'G (95% CI) in CFB		-0.17 (-0.48, 0.14)		-0.36 (-1.91, 1.01)	
p-value [3]		0.215		0.337	
					0.725

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Nausea Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	67	129	4	10	
Mean (StdDev)	3.34 (2.512)	2.93 (2.507)	3.73 (2.667)	3.07 (3.164)	
Median	2.79	2.46	3.39	2.93	
Min, Max	0.0, 8.9	0.0, 8.9	0.9, 7.2	0.0, 9.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Nausea Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	67	127	4	10	
Mean (StdDev)	2.82 (2.404)	2.53 (2.305)	3.61 (1.666)	2.86 (2.736)	
Median	2.29	2.00	3.39	3.04	
Min, Max	0.0, 8.3	0.0, 8.8	1.9, 5.8	0.0, 7.7	
C2D1 CFB					
n	67	125	4	10	
LS Mean (StdErr) [2]	-0.43 (0.161)	-0.34 (0.127)	0.25 (1.000)	0.11 (0.765)	
95% CI [2]	-0.75, -0.11	-0.59, -0.09	-1.97, 2.48	-1.59, 1.82	
Difference (95% CI) in CFB [2]		0.09 (-0.27, 0.45)		-0.14 (-1.99, 1.71)	
p-value [3]		0.619		0.871	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Nausea Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	67	125	4	10	
Mean (StdDev)	2.45 (2.328)	2.25 (2.220)	3.73 (1.448)	2.80 (2.618)	
Median	1.78	1.60	3.18	3.25	
Min, Max	0.0, 7.7	0.0, 8.9	2.7, 5.9	0.0, 6.8	
C3D1 CFB					
n	67	123	4	10	
LS Mean (StdErr) [2]	-0.79 (0.191)	-0.62 (0.151)	0.01 (1.246)	-0.34 (0.954)	
95% CI [2]	-1.17, -0.42	-0.92, -0.32	-2.77, 2.78	-2.46, 1.79	
Difference (95% CI) in CFB [2]		0.17 (-0.26, 0.60)		-0.34 (-2.65, 1.96)	
p-value [3]		0.428		0.747	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Nausea Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	64	125	4	10	
Mean (StdDev)	2.58 (2.290)	2.01 (2.222)	2.82 (1.434)	1.99 (2.219)	
Median	1.93	1.21	3.11	1.16	
Min, Max	0.0, 7.4	0.0, 9.2	0.9, 4.2	0.0, 6.0	
C4D1 CFB					
n	64	123	4	10	
LS Mean (StdErr) [2]	-0.82 (0.218)	-0.95 (0.168)	-0.39 (1.507)	-0.52 (1.154)	
95% CI [2]	-1.25, -0.38	-1.28, -0.61	-3.75, 2.97	-3.09, 2.05	
Difference (95% CI) in CFB [2]		-0.13 (-0.62, 0.36)		-0.13 (-2.92, 2.66)	
p-value [3]		0.597		0.920	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Nausea Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	63	127	4	10	
Mean (StdDev)	2.62 (2.294)	1.91 (2.119)	3.02 (0.602)	2.95 (3.159)	
Median	2.36	1.23	2.89	2.13	
Min, Max	0.0, 8.5	0.0, 8.9	2.4, 3.9	0.0, 7.6	
C5D1 CFB					
n	63	125	4	10	
LS Mean (StdErr) [2]	-0.77 (0.222)	-1.01 (0.168)	1.29 (2.175)	1.38 (1.666)	
95% CI [2]	-1.21, -0.33	-1.34, -0.68	-3.56, 6.14	-2.33, 5.09	
Difference (95% CI) in CFB [2]		-0.24 (-0.74, 0.25)		0.09 (-3.94, 4.11)	
p-value [3]		0.331		0.962	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Nausea Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	62	126	4	10	
Mean (StdDev)	2.23 (2.161)	1.73 (2.067)	3.48 (0.718)	2.47 (2.924)	
Median	1.64	1.22	3.64	1.48	
Min, Max	0.0, 7.9	0.0, 9.9	2.5, 4.1	0.0, 8.4	
C6D1 CFB					
n	62	124	4	10	
LS Mean (StdErr) [2]	-1.12 (0.235)	-1.19 (0.178)	1.20 (1.428)	0.63 (1.093)	
95% CI [2]	-1.58, -0.65	-1.54, -0.84	-1.98, 4.38	-1.80, 3.07	
Difference (95% CI) in CFB [2]		-0.07 (-0.60, 0.45)		-0.57 (-3.21, 2.08)	
p-value [3]		0.785		0.643	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Nausea Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	63	123	3	10	
Mean (StdDev)	2.36 (2.318)	1.80 (2.124)	3.43 (0.610)	2.18 (2.333)	
Median	1.36	1.14	3.50	1.55	
Min, Max	0.0, 7.7	0.0, 9.5	2.8, 4.0	0.0, 7.1	
C7D1 CFB					
n	63	121	3	10	
LS Mean (StdErr) [2]	-1.01 (0.253)	-1.10 (0.194)	1.37 (1.912)	0.40 (1.338)	
95% CI [2]	-1.51, -0.52	-1.48, -0.72	-2.95, 5.70	-2.63, 3.43	
Difference (95% CI) in CFB [2]		-0.09 (-0.65, 0.48)		-0.97 (-4.54, 2.60)	
Hedges'G (95% CI) in CFB		-0.04 (-0.35, 0.26)		-0.22 (-1.72, 1.18)	
p-value [3]		0.763		0.553	
					0.655

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Spots Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	67	129	4	10	
Mean (StdDev)	5.88 (3.045)	5.27 (3.022)	3.88 (4.516)	5.64 (3.364)	
Median	6.54	5.33	2.75	6.75	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 10.0	0.0, 9.4	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Spots Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	67	127	4	10	
Mean (StdDev)	5.50 (2.926)	4.41 (2.768)	3.59 (3.213)	4.82 (3.149)	
Median	5.71	4.38	3.71	5.29	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 6.9	0.0, 9.2	
C2D1 CFB					
n	67	125	4	10	
LS Mean (StdErr) [2]	-0.33 (0.160)	-0.85 (0.126)	0.36 (1.322)	-0.08 (1.012)	
95% CI [2]	-0.65, -0.01	-1.10, -0.60	-2.59, 3.30	-2.34, 2.17	
Difference (95% CI) in CFB [2]		-0.52 (-0.88, -0.16)		-0.44 (-2.88, 2.01)	
p-value [3]		0.005		0.698	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Spots Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	67	125	4	10	
Mean (StdDev)	5.49 (2.972)	4.01 (2.617)	3.02 (2.441)	4.44 (3.052)	
Median	5.50	3.86	3.32	5.39	
Min, Max	0.0, 10.0	0.0, 9.8	0.0, 5.4	0.0, 9.0	
C3D1 CFB					
n	67	123	4	10	
LS Mean (StdErr) [2]	-0.26 (0.200)	-1.20 (0.158)	0.09 (1.297)	-0.11 (0.993)	
95% CI [2]	-0.65, 0.14	-1.51, -0.89	-2.80, 2.98	-2.32, 2.10	
Difference (95% CI) in CFB [2]		-0.94 (-1.39, -0.49)		-0.20 (-2.60, 2.20)	
p-value [3]		<0.0001		0.858	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Spots Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	64	125	4	10	
Mean (StdDev)	5.39 (3.003)	3.81 (2.606)	3.02 (2.451)	4.06 (3.069)	
Median	5.50	3.57	3.18	4.27	
Min, Max	0.0, 10.0	0.0, 9.3	0.0, 5.7	0.0, 9.4	
C4D1 CFB					
n	64	123	4	10	
LS Mean (StdErr) [2]	-0.21 (0.206)	-1.31 (0.159)	0.34 (1.770)	-0.22 (1.355)	
95% CI [2]	-0.62, 0.19	-1.62, -0.99	-3.60, 4.29	-3.24, 2.79	
Difference (95% CI) in CFB [2]		-1.09 (-1.55, -0.64)		-0.57 (-3.84, 2.71)	
p-value [3]		<0.0001		0.707	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Spots Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	63	127	4	10	
Mean (StdDev)	5.29 (3.022)	3.63 (2.544)	2.44 (1.857)	3.72 (3.200)	
Median	5.14	3.14	2.92	3.04	
Min, Max	0.0, 10.0	0.0, 9.9	0.0, 3.9	0.1, 9.3	
C5D1 CFB					
n	63	125	4	10	
LS Mean (StdErr) [2]	-0.36 (0.222)	-1.53 (0.168)	0.10 (1.856)	-0.24 (1.421)	
95% CI [2]	-0.79, 0.08	-1.86, -1.20	-4.04, 4.23	-3.40, 2.93	
Difference (95% CI) in CFB [2]		-1.18 (-1.67, -0.68)		-0.33 (-3.77, 3.10)	
p-value [3]		<0.0001		0.833	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Spots Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	62	126	4	10	
Mean (StdDev)	5.36 (3.035)	3.50 (2.549)	2.54 (1.890)	3.23 (3.177)	
Median	5.11	3.19	2.86	2.57	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 4.4	0.0, 10.0	
C6D1 CFB					
n	62	124	4	10	
LS Mean (StdErr) [2]	-0.25 (0.263)	-1.56 (0.199)	0.60 (1.650)	-0.30 (1.264)	
95% CI [2]	-0.77, 0.27	-1.95, -1.17	-3.07, 4.28	-3.12, 2.51	
Difference (95% CI) in CFB [2]		-1.31 (-1.90, -0.72)		-0.91 (-3.96, 2.15)	
p-value [3]		<0.0001		0.523	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Spots Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	63	123	3	10	
Mean (StdDev)	5.30 (3.023)	3.50 (2.617)	3.76 (1.286)	3.21 (3.330)	
Median	5.00	3.17	3.71	2.39	
Min, Max	0.0, 10.0	0.0, 10.0	2.5, 5.1	0.0, 10.0	
C7D1 CFB					
n	63	121	3	10	
LS Mean (StdErr) [2]	-0.36 (0.261)	-1.62 (0.200)	0.84 (2.277)	-0.46 (1.593)	
95% CI [2]	-0.87, 0.16	-2.01, -1.22	-4.32, 5.99	-4.06, 3.15	
Difference (95% CI) in CFB [2]		-1.26 (-1.84, -0.68)		-1.29 (-5.55, 2.96)	
Hedges'G (95% CI) in CFB		-0.58 (-0.90, -0.28)		-0.25 (-1.76, 1.15)	
p-value [3]		<0.0001		0.508	
					0.863

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Itching Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	67	129	4	10	
Mean (StdDev)	5.82 (2.672)	5.03 (2.749)	3.93 (4.490)	6.41 (3.331)	
Median	6.36	5.07	2.86	7.14	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 10.0	0.5, 9.8	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Itching Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	67	127	4	10	
Mean (StdDev)	5.15 (2.770)	4.02 (2.416)	3.75 (3.495)	5.13 (3.321)	
Median	5.57	4.07	3.96	5.79	
Min, Max	0.0, 10.0	0.0, 9.9	0.0, 7.1	0.4, 9.4	
C2D1 CFB					
n	67	125	4	10	
LS Mean (StdErr) [2]	-0.68 (0.210)	-1.10 (0.165)	0.18 (1.345)	-0.92 (1.030)	
95% CI [2]	-1.10, -0.27	-1.42, -0.77	-2.82, 3.17	-3.22, 1.37	
Difference (95% CI) in CFB [2]		-0.41 (-0.88, 0.06)		-1.10 (-3.59, 1.39)	
p-value [3]		0.085		0.348	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Itching Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	67	125	4	10	
Mean (StdDev)	4.89 (2.800)	3.38 (2.344)	2.86 (2.729)	4.87 (3.758)	
Median	4.79	3.09	2.96	5.16	
Min, Max	0.0, 10.0	0.0, 8.9	0.0, 5.5	0.1, 9.7	
C3D1 CFB					
n	67	123	4	10	
LS Mean (StdErr) [2]	-0.84 (0.256)	-1.63 (0.202)	-0.05 (1.734)	-0.58 (1.328)	
95% CI [2]	-1.35, -0.34	-2.03, -1.23	-3.91, 3.81	-3.53, 2.38	
Difference (95% CI) in CFB [2]		-0.78 (-1.36, -0.21)		-0.52 (-3.73, 2.68)	
p-value [3]		0.008		0.723	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Itching Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	64	125	4	10	
Mean (StdDev)	4.79 (2.866)	3.17 (2.479)	2.84 (2.661)	4.64 (3.476)	
Median	5.14	3.07	2.79	4.14	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 5.8	0.7, 9.3	
C4D1 CFB					
n	64	123	4	10	
LS Mean (StdErr) [2]	-1.02 (0.299)	-1.89 (0.231)	-0.00 (2.073)	-0.52 (1.588)	
95% CI [2]	-1.61, -0.43	-2.35, -1.44	-4.62, 4.62	-4.05, 3.02	
Difference (95% CI) in CFB [2]		-0.87 (-1.54, -0.21)		-0.51 (-4.35, 3.32)	
p-value [3]		0.010		0.771	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Itching Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	63	127	4	10	
Mean (StdDev)	4.91 (2.751)	2.96 (2.403)	2.53 (2.315)	4.19 (3.733)	
Median	4.80	2.75	2.71	3.04	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 4.7	0.0, 9.3	
C5D1 CFB					
n	63	125	4	10	
LS Mean (StdErr) [2]	-0.88 (0.312)	-2.03 (0.236)	-0.08 (2.023)	-0.80 (1.549)	
95% CI [2]	-1.49, -0.26	-2.50, -1.57	-4.59, 4.43	-4.25, 2.65	
Difference (95% CI) in CFB [2]		-1.16 (-1.85, -0.46)		-0.72 (-4.46, 3.03)	
p-value [3]		0.001		0.678	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Itching Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	62	126	4	10	
Mean (StdDev)	4.85 (2.736)	2.92 (2.418)	2.52 (2.271)	4.14 (3.598)	
Median	4.88	2.64	2.50	2.64	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 5.1	0.4, 10.0	
C6D1 CFB					
n	62	124	4	10	
LS Mean (StdErr) [2]	-0.93 (0.326)	-2.11 (0.246)	-0.01 (1.648)	-0.73 (1.262)	
95% CI [2]	-1.57, -0.29	-2.60, -1.63	-3.68, 3.66	-3.54, 2.08	
Difference (95% CI) in CFB [2]		-1.18 (-1.91, -0.46)		-0.72 (-3.77, 2.32)	
p-value [3]		0.002		0.608	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Itching Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	63	123	3	10	
Mean (StdDev)	4.89 (2.676)	2.88 (2.382)	3.76 (1.967)	4.18 (3.727)	
Median	4.93	2.64	4.71	2.82	
Min, Max	0.0, 10.0	0.0, 10.0	1.5, 5.1	0.0, 10.0	
C7D1 CFB					
n	63	121	3	10	
LS Mean (StdErr) [2]	-0.90 (0.330)	-2.14 (0.253)	0.21 (2.165)	-0.76 (1.515)	
95% CI [2]	-1.55, -0.25	-2.64, -1.64	-4.68, 5.11	-4.19, 2.67	
Difference (95% CI) in CFB [2]		-1.24 (-1.98, -0.50)		-0.97 (-5.02, 3.07)	
Hedges'G (95% CI) in CFB		-0.45 (-0.77, -0.15)		-0.20 (-1.69, 1.21)	
p-value [3]		0.001		0.599	
					0.743

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Flushing Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	67	129	4	10	
Mean (StdDev)	5.79 (2.641)	5.07 (2.482)	4.46 (3.045)	5.16 (3.207)	
Median	5.77	5.14	5.50	5.26	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 6.9	0.0, 9.7	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Flushing Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	67	127	4	10	
Mean (StdDev)	5.24 (2.721)	4.40 (2.462)	4.05 (2.844)	4.16 (3.397)	
Median	4.86	4.43	4.82	4.39	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 6.6	0.0, 9.9	
C2D1 CFB					
n	67	125	4	10	
LS Mean (StdErr) [2]	-0.57 (0.198)	-0.71 (0.156)	0.28 (0.817)	-0.32 (0.626)	
95% CI [2]	-0.96, -0.18	-1.02, -0.41	-1.54, 2.10	-1.72, 1.07	
Difference (95% CI) in CFB [2]		-0.15 (-0.59, 0.30)		-0.60 (-2.12, 0.91)	
p-value [3]		0.518		0.395	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Flushing Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	67	125	4	10	
Mean (StdDev)	5.01 (2.874)	3.88 (2.423)	4.36 (3.115)	4.41 (3.322)	
Median	5.00	3.79	5.04	4.11	
Min, Max	0.0, 10.0	0.0, 10.0	0.0, 7.4	0.6, 10.0	
C3D1 CFB					
n	67	123	4	10	
LS Mean (StdErr) [2]	-0.69 (0.237)	-1.15 (0.187)	0.69 (1.105)	0.09 (0.846)	
95% CI [2]	-1.15, -0.22	-1.52, -0.78	-1.77, 3.16	-1.79, 1.98	
Difference (95% CI) in CFB [2]		-0.46 (-0.99, 0.07)		-0.60 (-2.65, 1.44)	
p-value [3]		0.088		0.527	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Flushing Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	64	125	4	10	
Mean (StdDev)	5.04 (2.892)	3.66 (2.466)	3.96 (3.003)	4.32 (3.197)	
Median	4.57	3.54	4.29	3.92	
Min, Max	0.1, 10.0	0.0, 10.0	0.0, 7.3	1.0, 9.9	
C4D1 CFB					
n	64	123	4	10	
LS Mean (StdErr) [2]	-0.72 (0.270)	-1.42 (0.209)	0.32 (1.475)	0.21 (1.129)	
95% CI [2]	-1.25, -0.19	-1.83, -1.00	-2.96, 3.61	-2.31, 2.73	
Difference (95% CI) in CFB [2]		-0.70 (-1.30, -0.09)		-0.11 (-2.84, 2.62)	
p-value [3]		0.024		0.929	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Flushing Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	63	127	4	10	
Mean (StdDev)	5.03 (2.936)	3.49 (2.424)	3.86 (2.888)	4.90 (3.267)	
Median	5.00	3.50	4.21	3.87	
Min, Max	0.0, 10.0	0.0, 9.7	0.0, 7.0	0.3, 9.8	
C5D1 CFB					
n	63	125	4	10	
LS Mean (StdErr) [2]	-0.77 (0.299)	-1.64 (0.226)	1.20 (1.575)	1.48 (1.206)	
95% CI [2]	-1.36, -0.18	-2.09, -1.20	-2.31, 4.71	-1.21, 4.17	
Difference (95% CI) in CFB [2]		-0.87 (-1.53, -0.20)		0.28 (-2.63, 3.20)	
p-value [3]		0.011		0.833	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Flushing Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	62	126	4	10	
Mean (StdDev)	4.92 (2.944)	3.37 (2.452)	3.61 (2.866)	4.24 (3.362)	
Median	5.00	3.30	3.71	2.65	
Min, Max	0.0, 10.0	0.0, 9.8	0.0, 7.0	0.1, 10.0	
C6D1 CFB					
n	62	124	4	10	
LS Mean (StdErr) [2]	-0.90 (0.312)	-1.74 (0.236)	0.94 (1.275)	0.83 (0.976)	
95% CI [2]	-1.52, -0.28	-2.20, -1.27	-1.90, 3.78	-1.35, 3.00	
Difference (95% CI) in CFB [2]		-0.84 (-1.54, -0.14)		-0.11 (-2.47, 2.25)	
p-value [3]		0.018		0.917	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Flushing Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	63	123	3	10	
Mean (StdDev)	4.93 (2.924)	3.18 (2.389)	4.60 (1.985)	4.23 (3.474)	
Median	4.75	2.79	3.79	3.14	
Min, Max	0.0, 10.0	0.0, 9.6	3.1, 6.9	0.0, 10.0	
C7D1 CFB					
n	63	121	3	10	
LS Mean (StdErr) [2]	-0.81 (0.319)	-1.79 (0.245)	0.43 (1.473)	0.58 (1.030)	
95% CI [2]	-1.44, -0.18	-2.27, -1.31	-2.90, 3.76	-1.75, 2.91	
Difference (95% CI) in CFB [2]		-0.98 (-1.70, -0.27)		0.15 (-2.60, 2.90)	
Hedges'G (95% CI) in CFB		-0.37 (-0.68, -0.07)		0.05 (-1.39, 1.50)	
p-value [3]		0.007		0.903	
					0.357

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Fatigue Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	67	129	4	10	
Mean (StdDev)	6.65 (1.985)	6.59 (2.128)	7.80 (2.484)	7.42 (1.938)	
Median	6.62	6.86	8.39	7.14	
Min, Max	0.0, 10.0	0.1, 10.0	4.4, 10.0	4.2, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Fatigue Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	67	127	4	10	
Mean (StdDev)	6.24 (1.994)	5.87 (2.302)	7.23 (1.586)	7.10 (2.244)	
Median	6.29	6.14	7.96	7.23	
Min, Max	2.3, 10.0	0.1, 10.0	4.9, 8.1	3.2, 10.0	
C2D1 CFB					
n	67	125	4	10	
LS Mean (StdErr) [2]	-0.44 (0.161)	-0.77 (0.127)	-0.61 (0.927)	-0.38 (0.710)	
95% CI [2]	-0.76, -0.12	-1.02, -0.52	-2.67, 1.46	-1.96, 1.20	
Difference (95% CI) in CFB [2]		-0.33 (-0.69, 0.03)		0.23 (-1.49, 1.94)	
p-value [3]		0.074		0.774	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Fatigue Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	67	125	4	10	
Mean (StdDev)	5.85 (2.330)	5.44 (2.336)	7.09 (2.305)	6.93 (2.183)	
Median	5.86	5.46	7.89	7.11	
Min, Max	0.3, 10.0	0.2, 10.0	3.7, 8.9	3.1, 10.0	
C3D1 CFB					
n	67	123	4	10	
LS Mean (StdErr) [2]	-0.81 (0.208)	-1.16 (0.164)	-0.94 (1.122)	-0.76 (0.859)	
95% CI [2]	-1.22, -0.40	-1.48, -0.83	-3.44, 1.56	-2.67, 1.16	
Difference (95% CI) in CFB [2]		-0.34 (-0.81, 0.12)		0.18 (-1.90, 2.26)	
p-value [3]		0.149		0.851	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Fatigue Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	64	125	4	10	
Mean (StdDev)	5.61 (2.457)	5.16 (2.465)	6.93 (1.994)	6.77 (2.386)	
Median	5.82	5.14	7.25	7.70	
Min, Max	0.2, 10.0	0.0, 10.0	4.3, 8.9	2.2, 10.0	
C4D1 CFB					
n	64	123	4	10	
LS Mean (StdErr) [2]	-1.05 (0.253)	-1.47 (0.195)	-1.12 (1.568)	-0.91 (1.200)	
95% CI [2]	-1.55, -0.55	-1.86, -1.09	-4.61, 2.37	-3.59, 1.76	
Difference (95% CI) in CFB [2]		-0.43 (-0.99, 0.14)		0.21 (-2.69, 3.11)	
p-value [3]		0.138		0.877	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Fatigue Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	63	127	4	10	
Mean (StdDev)	5.52 (2.474)	5.10 (2.415)	6.22 (1.889)	6.83 (2.749)	
Median	5.21	5.29	6.25	7.38	
Min, Max	0.6, 10.0	0.0, 10.0	3.9, 8.5	1.9, 10.0	
C5D1 CFB					
n	63	125	4	10	
LS Mean (StdErr) [2]	-1.06 (0.260)	-1.45 (0.196)	-1.79 (1.882)	-0.89 (1.441)	
95% CI [2]	-1.58, -0.55	-1.84, -1.06	-5.99, 2.40	-4.10, 2.32	
Difference (95% CI) in CFB [2]		-0.39 (-0.96, 0.19)		0.90 (-2.58, 4.39)	
p-value [3]		0.187		0.576	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Fatigue Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	62	126	4	10	
Mean (StdDev)	5.55 (2.477)	4.89 (2.609)	6.57 (1.719)	6.54 (2.795)	
Median	5.40	5.04	6.61	7.43	
Min, Max	0.4, 10.0	0.0, 10.0	4.5, 8.6	1.0, 10.0	
C6D1 CFB					
n	62	124	4	10	
LS Mean (StdErr) [2]	-0.96 (0.285)	-1.61 (0.215)	-1.46 (1.706)	-1.21 (1.306)	
95% CI [2]	-1.53, -0.40	-2.04, -1.19	-5.26, 2.34	-4.12, 1.70	
Difference (95% CI) in CFB [2]		-0.65 (-1.28, -0.01)		0.25 (-2.91, 3.41)	
p-value [3]		0.046		0.864	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Fatigue Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	63	123	3	10	
Mean (StdDev)	5.52 (2.539)	4.80 (2.538)	6.86 (1.777)	5.93 (3.008)	
Median	5.46	5.07	7.21	6.50	
Min, Max	0.2, 10.0	0.0, 10.0	4.9, 8.4	1.4, 10.0	
C7D1 CFB					
n	63	121	3	10	
LS Mean (StdErr) [2]	-0.99 (0.289)	-1.70 (0.222)	-1.62 (1.817)	-1.13 (1.271)	
95% CI [2]	-1.56, -0.42	-2.14, -1.26	-5.73, 2.49	-4.00, 1.75	
Difference (95% CI) in CFB [2]		-0.70 (-1.35, -0.06)		0.50 (-2.89, 3.89)	
Hedges'G (95% CI) in CFB		-0.29 (-0.60, 0.01)		0.12 (-1.30, 1.60)	
p-value [3]		0.033		0.748	
					0.358

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Dizziness Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	67	129	4	10	
Mean (StdDev)	3.58 (2.730)	3.60 (2.879)	3.50 (3.744)	4.25 (2.805)	
Median	2.86	3.50	2.79	4.46	
Min, Max	0.0, 9.3	0.0, 10.0	0.0, 8.4	0.0, 9.8	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Dizziness Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	67	127	4	10	
Mean (StdDev)	3.11 (2.665)	3.01 (2.612)	3.23 (2.629)	4.16 (3.221)	
Median	2.46	2.58	3.25	4.54	
Min, Max	0.0, 8.7	0.0, 10.0	0.0, 6.4	0.0, 10.0	
C2D1 CFB					
n	67	125	4	10	
LS Mean (StdErr) [2]	-0.41 (0.178)	-0.58 (0.140)	-0.02 (1.083)	0.03 (0.829)	
95% CI [2]	-0.76, -0.06	-0.86, -0.30	-2.43, 2.39	-1.82, 1.88	
Difference (95% CI) in CFB [2]		-0.17 (-0.57, 0.22)		0.05 (-1.95, 2.06)	
p-value [3]		0.388		0.954	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Dizziness Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	67	125	4	10	
Mean (StdDev)	2.73 (2.589)	2.70 (2.604)	3.38 (2.229)	3.52 (3.393)	
Median	2.00	2.08	3.75	4.00	
Min, Max	0.0, 8.1	0.0, 10.0	0.4, 5.6	0.0, 10.0	
C3D1 CFB					
n	67	123	4	10	
LS Mean (StdErr) [2]	-0.76 (0.208)	-0.87 (0.164)	0.60 (1.398)	-0.07 (1.070)	
95% CI [2]	-1.17, -0.35	-1.19, -0.55	-2.51, 3.72	-2.45, 2.32	
Difference (95% CI) in CFB [2]		-0.11 (-0.58, 0.35)		-0.67 (-3.25, 1.92)	
p-value [3]		0.629		0.577	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Dizziness Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	64	125	4	10	
Mean (StdDev)	2.90 (2.685)	2.60 (2.659)	3.02 (2.122)	3.62 (3.240)	
Median	2.25	1.92	3.75	3.74	
Min, Max	0.0, 9.9	0.0, 10.0	0.0, 4.6	0.0, 10.0	
C4D1 CFB					
n	64	123	4	10	
LS Mean (StdErr) [2]	-0.63 (0.252)	-1.02 (0.195)	-0.07 (1.421)	-0.19 (1.088)	
95% CI [2]	-1.12, -0.13	-1.40, -0.63	-3.24, 3.10	-2.61, 2.24	
Difference (95% CI) in CFB [2]		-0.39 (-0.95, 0.17)		-0.12 (-2.75, 2.51)	
p-value [3]		0.170		0.922	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Dizziness Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	63	127	4	10	
Mean (StdDev)	2.91 (2.654)	2.44 (2.528)	3.24 (1.583)	3.88 (3.567)	
Median	2.31	1.79	3.29	3.31	
Min, Max	0.0, 9.6	0.0, 9.6	1.5, 4.9	0.0, 10.0	
C5D1 CFB					
n	63	125	4	10	
LS Mean (StdErr) [2]	-0.57 (0.243)	-1.10 (0.184)	1.70 (1.500)	1.19 (1.149)	
95% CI [2]	-1.05, -0.09	-1.46, -0.74	-1.64, 5.04	-1.37, 3.75	
Difference (95% CI) in CFB [2]		-0.53 (-1.08, 0.01)		-0.52 (-3.29, 2.26)	
p-value [3]		0.053		0.688	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Dizziness Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	62	126	4	10	
Mean (StdDev)	2.65 (2.638)	2.21 (2.405)	3.41 (1.860)	3.54 (3.583)	
Median	1.69	1.52	3.50	3.43	
Min, Max	0.0, 8.6	0.0, 9.8	1.2, 5.4	0.0, 10.0	
C6D1 CFB					
n	62	124	4	10	
LS Mean (StdErr) [2]	-0.85 (0.263)	-1.32 (0.199)	1.72 (1.440)	0.78 (1.103)	
95% CI [2]	-1.37, -0.33	-1.71, -0.93	-1.49, 4.93	-1.68, 3.23	
Difference (95% CI) in CFB [2]		-0.47 (-1.06, 0.12)		-0.94 (-3.60, 1.73)	
p-value [3]		0.116		0.450	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Dizziness Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	63	123	3	10	
Mean (StdDev)	2.67 (2.684)	2.22 (2.448)	3.81 (1.075)	3.55 (3.430)	
Median	1.79	1.50	4.36	3.00	
Min, Max	0.0, 10.0	0.0, 9.8	2.6, 4.5	0.0, 10.0	
C7D1 CFB					
n	63	121	3	10	
LS Mean (StdErr) [2]	-0.88 (0.270)	-1.29 (0.207)	2.21 (1.809)	0.65 (1.265)	
95% CI [2]	-1.41, -0.35	-1.70, -0.88	-1.88, 6.30	-2.21, 3.52	
Difference (95% CI) in CFB [2]		-0.40 (-1.01, 0.20)		-1.56 (-4.94, 1.82)	
Hedges'G (95% CI) in CFB		-0.18 (-0.49, 0.12)		-0.38 (-1.92, 1.00)	
p-value [3]		0.188		0.323	
					0.554

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Brain Fog Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	67	129	4	10	
Mean (StdDev)	4.99 (2.726)	5.38 (2.503)	5.70 (3.390)	5.29 (2.650)	
Median	5.08	5.54	6.50	5.43	
Min, Max	0.0, 10.0	0.0, 10.0	1.3, 8.5	0.0, 9.9	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Brain Fog Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	67	127	4	10	
Mean (StdDev)	4.50 (2.691)	4.73 (2.677)	5.11 (2.360)	4.79 (2.895)	
Median	4.21	4.64	5.43	4.43	
Min, Max	0.0, 10.0	0.0, 10.0	2.4, 7.2	0.0, 10.0	
C2D1 CFB					
n	67	125	4	10	
LS Mean (StdErr) [2]	-0.47 (0.152)	-0.67 (0.120)	-0.16 (1.002)	-0.22 (0.767)	
95% CI [2]	-0.77, -0.17	-0.90, -0.43	-2.39, 2.08	-1.93, 1.49	
Difference (95% CI) in CFB [2]		-0.20 (-0.54, 0.14)		-0.06 (-1.91, 1.79)	
p-value [3]		0.251		0.943	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Brain Fog Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	67	125	4	10	
Mean (StdDev)	4.28 (2.772)	4.38 (2.697)	4.68 (2.032)	4.79 (3.149)	
Median	3.93	4.31	4.50	4.56	
Min, Max	0.0, 10.0	0.0, 10.0	2.8, 6.9	0.0, 10.0	
C3D1 CFB					
n	67	123	4	10	
LS Mean (StdErr) [2]	-0.67 (0.179)	-1.03 (0.141)	-0.30 (1.369)	-0.06 (1.048)	
95% CI [2]	-1.03, -0.32	-1.31, -0.75	-3.35, 2.75	-2.40, 2.27	
Difference (95% CI) in CFB [2]		-0.36 (-0.76, 0.04)		0.23 (-2.30, 2.77)	
p-value [3]		0.080		0.841	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Brain Fog Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	64	125	4	10	
Mean (StdDev)	4.08 (2.852)	4.15 (2.803)	4.43 (1.754)	4.64 (3.351)	
Median	3.89	3.86	3.89	4.11	
Min, Max	0.0, 10.0	0.0, 10.0	3.1, 6.9	0.0, 9.9	
C4D1 CFB					
n	64	123	4	10	
LS Mean (StdErr) [2]	-0.88 (0.223)	-1.25 (0.172)	-0.47 (1.740)	-0.11 (1.332)	
95% CI [2]	-1.32, -0.44	-1.59, -0.91	-4.34, 3.41	-3.08, 2.86	
Difference (95% CI) in CFB [2]		-0.37 (-0.87, 0.12)		0.35 (-2.86, 3.57)	
p-value [3]		0.140		0.811	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Brain Fog Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	63	127	4	10	
Mean (StdDev)	3.87 (2.829)	4.11 (2.776)	4.62 (2.188)	4.92 (3.780)	
Median	3.43	4.43	4.21	4.74	
Min, Max	0.0, 10.0	0.0, 10.0	2.5, 7.5	0.0, 10.0	
C5D1 CFB					
n	63	125	4	10	
LS Mean (StdErr) [2]	-0.98 (0.237)	-1.19 (0.179)	0.22 (2.113)	0.48 (1.618)	
95% CI [2]	-1.45, -0.51	-1.54, -0.84	-4.49, 4.93	-3.12, 4.09	
Difference (95% CI) in CFB [2]		-0.21 (-0.74, 0.32)		0.26 (-3.65, 4.17)	
p-value [3]		0.430		0.884	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Brain Fog Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	62	126	4	10	
Mean (StdDev)	3.91 (2.814)	3.98 (2.840)	4.86 (1.669)	4.18 (3.574)	
Median	3.64	3.58	4.64	3.71	
Min, Max	0.0, 10.0	0.0, 10.0	3.4, 6.8	0.0, 10.0	
C6D1 CFB					
n	62	124	4	10	
LS Mean (StdErr) [2]	-0.88 (0.241)	-1.32 (0.182)	0.57 (1.656)	-0.08 (1.268)	
95% CI [2]	-1.36, -0.41	-1.68, -0.96	-3.12, 4.26	-2.90, 2.74	
Difference (95% CI) in CFB [2]		-0.44 (-0.97, 0.10)		-0.65 (-3.71, 2.42)	
p-value [3]		0.112		0.648	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Brain Fog Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	63	123	3	10	
Mean (StdDev)	3.95 (2.897)	3.92 (2.884)	5.02 (1.858)	4.01 (3.542)	
Median	3.57	3.82	5.07	3.07	
Min, Max	0.0, 10.0	0.0, 10.0	3.1, 6.9	0.0, 10.0	
C7D1 CFB					
n	63	121	3	10	
LS Mean (StdErr) [2]	-0.90 (0.253)	-1.37 (0.194)	0.37 (1.873)	-0.21 (1.310)	
95% CI [2]	-1.39, -0.40	-1.75, -0.98	-3.86, 4.61	-3.17, 2.75	
Difference (95% CI) in CFB [2]		-0.47 (-1.04, 0.09)		-0.58 (-4.08, 2.92)	
Hedges'G (95% CI) in CFB		-0.22 (-0.53, 0.08)		-0.14 (-1.62, 1.28)	
p-value [3]		0.102		0.716	
					0.874

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Headache Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	67	129	4	10	
Mean (StdDev)	4.08 (2.785)	3.95 (2.489)	4.45 (0.741)	4.85 (3.348)	
Median	4.36	3.86	4.25	4.93	
Min, Max	0.0, 9.9	0.0, 9.7	3.8, 5.5	0.8, 9.9	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Headache Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	67	127	4	10	
Mean (StdDev)	3.76 (2.653)	3.42 (2.349)	4.04 (1.450)	4.14 (3.427)	
Median	3.50	3.21	3.82	3.21	
Min, Max	0.0, 9.1	0.0, 8.6	2.5, 6.0	0.1, 10.0	
C2D1 CFB					
n	67	125	4	10	
LS Mean (StdErr) [2]	-0.32 (0.164)	-0.56 (0.129)	0.07 (0.950)	-0.39 (0.727)	
95% CI [2]	-0.64, 0.01	-0.82, -0.31	-2.05, 2.18	-2.01, 1.23	
Difference (95% CI) in CFB [2]		-0.25 (-0.62, 0.12)		-0.46 (-2.21, 1.30)	
p-value [3]		0.188		0.575	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Headache Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	67	125	4	10	
Mean (StdDev)	3.38 (2.623)	3.09 (2.281)	3.96 (1.387)	3.85 (3.674)	
Median	2.69	2.62	3.93	3.18	
Min, Max	0.0, 9.1	0.0, 8.3	2.4, 5.6	0.2, 10.0	
C3D1 CFB					
n	67	123	4	10	
LS Mean (StdErr) [2]	-0.66 (0.212)	-0.85 (0.167)	0.20 (1.211)	-0.47 (0.927)	
95% CI [2]	-1.08, -0.24	-1.18, -0.52	-2.50, 2.89	-2.53, 1.60	
Difference (95% CI) in CFB [2]		-0.19 (-0.67, 0.29)		-0.66 (-2.90, 1.58)	
p-value [3]		0.430		0.526	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Headache Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	64	125	4	10	
Mean (StdDev)	3.42 (2.542)	2.92 (2.240)	4.27 (1.284)	3.91 (3.744)	
Median	3.07	2.71	4.29	2.57	
Min, Max	0.0, 8.4	0.0, 7.7	2.8, 5.7	0.0, 9.9	
C4D1 CFB					
n	64	123	4	10	
LS Mean (StdErr) [2]	-0.70 (0.238)	-1.08 (0.184)	0.78 (1.032)	-0.19 (0.790)	
95% CI [2]	-1.17, -0.23	-1.44, -0.72	-1.52, 3.08	-1.95, 1.57	
Difference (95% CI) in CFB [2]		-0.38 (-0.91, 0.15)		-0.97 (-2.88, 0.94)	
p-value [3]		0.160		0.286	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Headache Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	63	127	4	10	
Mean (StdDev)	3.42 (2.524)	2.80 (2.155)	3.41 (1.945)	4.09 (4.261)	
Median	2.79	2.45	3.83	2.66	
Min, Max	0.0, 9.1	0.0, 8.4	0.7, 5.3	0.0, 10.0	
C5D1 CFB					
n	63	125	4	10	
LS Mean (StdErr) [2]	-0.76 (0.229)	-1.23 (0.173)	0.30 (1.473)	0.01 (1.127)	
95% CI [2]	-1.21, -0.31	-1.58, -0.89	-2.98, 3.58	-2.50, 2.52	
Difference (95% CI) in CFB [2]		-0.47 (-0.98, 0.04)		-0.29 (-3.01, 2.43)	
p-value [3]		0.069		0.817	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Headache Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	62	126	4	10	
Mean (StdDev)	3.09 (2.545)	2.59 (2.224)	3.82 (1.095)	3.75 (4.093)	
Median	2.64	2.04	3.57	1.29	
Min, Max	0.0, 8.9	0.0, 10.0	2.8, 5.4	0.1, 10.0	
C6D1 CFB					
n	62	124	4	10	
LS Mean (StdErr) [2]	-0.96 (0.244)	-1.40 (0.184)	0.76 (1.120)	-0.11 (0.857)	
95% CI [2]	-1.45, -0.48	-1.77, -1.04	-1.73, 3.26	-2.02, 1.80	
Difference (95% CI) in CFB [2]		-0.44 (-0.99, 0.10)		-0.87 (-2.94, 1.20)	
p-value [3]		0.112		0.370	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Headache Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	63	123	3	10	
Mean (StdDev)	3.17 (2.629)	2.56 (2.182)	4.17 (1.053)	3.88 (3.958)	
Median	2.43	2.00	3.79	2.11	
Min, Max	0.0, 8.9	0.0, 9.6	3.4, 5.4	0.0, 10.0	
C7D1 CFB					
n	63	121	3	10	
LS Mean (StdErr) [2]	-0.88 (0.244)	-1.39 (0.187)	0.45 (1.461)	-0.25 (1.022)	
95% CI [2]	-1.36, -0.40	-1.76, -1.02	-2.86, 3.75	-2.56, 2.06	
Difference (95% CI) in CFB [2]		-0.51 (-1.06, 0.03)		-0.70 (-3.43, 2.03)	
Hedges'G (95% CI) in CFB		-0.25 (-0.56, 0.05)		-0.21 (-1.71, 1.20)	
p-value [3]		0.065		0.576	
					0.931

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Count

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	67	129	4	10	
Mean (StdDev)	1.52 (1.504)	1.43 (1.637)	1.09 (0.868)	1.60 (1.842)	
Median	1.14	1.00	1.25	0.96	
Min, Max	0.0, 7.2	0.0, 12.2	0.0, 1.9	0.0, 5.4	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Count

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	67	127	4	10	
Mean (StdDev)	1.25 (1.301)	1.10 (1.405)	0.95 (0.763)	1.13 (1.583)	
Median	0.64	0.69	0.75	0.68	
Min, Max	0.0, 4.9	0.0, 10.7	0.3, 2.0	0.0, 4.8	
C2D1 CFB					
n	67	125	4	10	
LS Mean (StdErr) [2]	-0.34 (0.109)	-0.43 (0.086)	0.12 (0.766)	-0.25 (0.587)	
95% CI [2]	-0.55, -0.12	-0.60, -0.26	-1.59, 1.83	-1.55, 1.06	
Difference (95% CI) in CFB [2]		-0.09 (-0.33, 0.16)		-0.37 (-1.79, 1.05)	
p-value [3]		0.476		0.575	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Count

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	67	125	4	10	
Mean (StdDev)	1.12 (1.194)	0.99 (1.183)	1.29 (0.456)	0.87 (1.226)	
Median	0.64	0.67	1.14	0.36	
Min, Max	0.0, 4.4	0.0, 5.8	0.9, 1.9	0.0, 3.8	
C3D1 CFB					
n	67	123	4	10	
LS Mean (StdErr) [2]	-0.49 (0.139)	-0.55 (0.110)	0.61 (1.209)	-0.40 (0.925)	
95% CI [2]	-0.77, -0.22	-0.77, -0.34	-2.09, 3.30	-2.46, 1.66	
Difference (95% CI) in CFB [2]		-0.06 (-0.37, 0.25)		-1.01 (-3.25, 1.23)	
p-value [3]		0.700		0.338	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Count	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	64	125	4	10	
Mean (StdDev)	1.10 (1.143)	0.99 (1.318)	1.48 (1.027)	1.00 (1.948)	
Median	0.68	0.54	1.14	0.21	
Min, Max	0.0, 4.8	0.0, 9.0	0.7, 2.9	0.0, 6.2	
C4D1 CFB					
n	64	123	4	10	
LS Mean (StdErr) [2]	-0.54 (0.133)	-0.54 (0.102)	0.80 (1.299)	-0.20 (0.994)	
95% CI [2]	-0.80, -0.28	-0.74, -0.34	-2.10, 3.69	-2.41, 2.02	
Difference (95% CI) in CFB [2]		0.00 (-0.29, 0.30)		-0.99 (-3.40, 1.41)	
p-value [3]		0.998		0.379	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Count	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	63	127	4	10	
Mean (StdDev)	1.16 (1.209)	0.95 (1.280)	0.79 (0.810)	1.55 (2.795)	
Median	0.57	0.50	0.64	0.07	
Min, Max	0.0, 4.8	0.0, 9.6	0.0, 1.9	0.0, 8.1	
C5D1 CFB					
n	63	125	4	10	
LS Mean (StdErr) [2]	-0.47 (0.144)	-0.60 (0.109)	-0.27 (1.835)	-0.02 (1.405)	
95% CI [2]	-0.76, -0.19	-0.82, -0.39	-4.36, 3.82	-3.15, 3.11	
Difference (95% CI) in CFB [2]		-0.13 (-0.45, 0.19)		0.25 (-3.15, 3.65)	
p-value [3]		0.418		0.873	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Count

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	62	126	4	10	
Mean (StdDev)	1.05 (1.280)	0.92 (1.253)	1.04 (1.227)	0.86 (1.681)	
Median	0.64	0.46	0.68	0.04	
Min, Max	0.0, 6.5	0.0, 9.0	0.0, 2.8	0.0, 5.2	
C6D1 CFB					
n	62	124	4	10	
LS Mean (StdErr) [2]	-0.53 (0.131)	-0.59 (0.099)	0.48 (1.195)	-0.17 (0.915)	
95% CI [2]	-0.79, -0.27	-0.78, -0.39	-2.18, 3.14	-2.21, 1.87	
Difference (95% CI) in CFB [2]		-0.06 (-0.35, 0.23)		-0.65 (-2.86, 1.56)	
p-value [3]		0.682		0.526	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Count

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	63	123	3	10	
Mean (StdDev)	1.08 (1.255)	0.83 (1.070)	0.38 (0.393)	0.82 (1.507)	
Median	0.50	0.29	0.36	0.18	
Min, Max	0.0, 5.9	0.0, 4.3	0.0, 0.8	0.0, 4.8	
C7D1 CFB					
n	63	121	3	10	
LS Mean (StdErr) [2]	-0.47 (0.145)	-0.58 (0.111)	0.12 (1.278)	-0.29 (0.894)	
95% CI [2]	-0.76, -0.19	-0.80, -0.36	-2.77, 3.01	-2.32, 1.73	
Difference (95% CI) in CFB [2]		-0.11 (-0.43, 0.21)		-0.42 (-2.80, 1.97)	
Hedges'G (95% CI) in CFB		-0.09 (-0.40, 0.21)		-0.14 (-1.63, 1.28)	
p-value [3]		0.505		0.701	
					0.802

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	67	129	4	10	
Mean (StdDev)	3.08 (2.583)	2.87 (2.373)	2.89 (3.455)	3.14 (2.805)	
Median	2.36	2.40	1.86	2.49	
Min, Max	0.0, 9.5	0.0, 9.5	0.0, 7.9	0.0, 7.7	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Severity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	67	127	4	10	
Mean (StdDev)	2.42 (2.442)	2.27 (2.314)	1.68 (1.115)	2.64 (2.712)	
Median	1.79	1.40	1.71	1.89	
Min, Max	0.0, 9.1	0.0, 8.9	0.6, 2.6	0.0, 7.4	
C2D1 CFB					
n	67	125	4	10	
LS Mean (StdErr) [2]	-0.57 (0.180)	-0.56 (0.141)	-0.78 (1.370)	0.02 (1.049)	
95% CI [2]	-0.93, -0.22	-0.84, -0.28	-3.83, 2.27	-2.32, 2.35	
Difference (95% CI) in CFB [2]		0.01 (-0.39, 0.41)		0.80 (-1.73, 3.33)	
p-value [3]		0.960		0.498	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	67	125	4	10	
Mean (StdDev)	2.23 (2.337)	2.08 (2.206)	2.43 (1.008)	2.18 (2.740)	
Median	1.43	1.21	2.18	0.68	
Min, Max	0.0, 8.7	0.0, 9.5	1.5, 3.9	0.0, 7.7	
C3D1 CFB					
n	67	123	4	10	
LS Mean (StdErr) [2]	-0.76 (0.219)	-0.75 (0.172)	0.12 (1.769)	-0.42 (1.354)	
95% CI [2]	-1.19, -0.33	-1.09, -0.41	-3.82, 4.07	-3.44, 2.59	
Difference (95% CI) in CFB [2]		0.01 (-0.48, 0.50)		-0.55 (-3.82, 2.72)	
p-value [3]		0.963		0.717	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	64	125	4	10	
Mean (StdDev)	2.40 (2.397)	2.03 (2.226)	2.61 (1.515)	1.84 (2.842)	
Median	1.44	1.18	2.39	0.54	
Min, Max	0.0, 8.3	0.0, 8.3	1.0, 4.6	0.0, 8.9	
C4D1 CFB					
n	64	123	4	10	
LS Mean (StdErr) [2]	-0.69 (0.213)	-0.83 (0.165)	0.66 (1.946)	-0.29 (1.490)	
95% CI [2]	-1.12, -0.27	-1.15, -0.50	-3.67, 5.00	-3.61, 3.03	
Difference (95% CI) in CFB [2]		-0.13 (-0.61, 0.34)		-0.95 (-4.55, 2.65)	
p-value [3]		0.576		0.571	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	63	127	4	10	
Mean (StdDev)	2.46 (2.397)	1.92 (2.059)	1.32 (1.254)	2.41 (3.698)	
Median	1.36	1.21	1.43	0.33	
Min, Max	0.0, 8.5	0.0, 8.0	0.0, 2.4	0.0, 9.0	
C5D1 CFB					
n	63	125	4	10	
LS Mean (StdErr) [2]	-0.65 (0.243)	-0.97 (0.184)	-0.99 (2.038)	-0.06 (1.561)	
95% CI [2]	-1.13, -0.17	-1.33, -0.61	-5.53, 3.55	-3.54, 3.42	
Difference (95% CI) in CFB [2]		-0.32 (-0.86, 0.22)		0.93 (-2.84, 4.70)	
p-value [3]		0.241		0.594	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	62	126	4	10	
Mean (StdDev)	2.22 (2.381)	1.83 (2.129)	1.70 (1.634)	1.60 (2.709)	
Median	1.29	1.14	1.43	0.07	
Min, Max	0.0, 8.6	0.0, 8.9	0.0, 3.9	0.0, 8.1	
C6D1 CFB					
n	62	124	4	10	
LS Mean (StdErr) [2]	-0.72 (0.228)	-0.97 (0.172)	-0.02 (1.875)	-0.23 (1.435)	
95% CI [2]	-1.17, -0.27	-1.31, -0.63	-4.20, 4.15	-3.43, 2.97	
Difference (95% CI) in CFB [2]		-0.24 (-0.75, 0.26)		-0.21 (-3.68, 3.26)	
p-value [3]		0.344		0.897	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.7a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by ECOG Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Severity	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	63	123	3	10	
Mean (StdDev)	2.25 (2.461)	1.78 (2.150)	0.95 (1.242)	1.70 (2.728)	
Median	1.36	0.71	0.50	0.36	
Min, Max	0.0, 8.6	0.0, 8.7	0.0, 2.4	0.0, 8.4	
C7D1 CFB					
n	63	121	3	10	
LS Mean (StdErr) [2]	-0.69 (0.251)	-0.98 (0.193)	-0.95 (1.885)	-0.46 (1.318)	
95% CI [2]	-1.19, -0.20	-1.36, -0.60	-5.21, 3.31	-3.44, 2.53	
Difference (95% CI) in CFB [2]		-0.29 (-0.85, 0.28)		0.49 (-3.02, 4.01)	
Hedges'G (95% CI) in CFB		-0.14 (-0.45, 0.17)		0.11 (-1.31, 1.59)	
p-value [3]		0.315		0.758	
					0.445

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-ecog-a.sas Date: 14:59/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Bone Pain Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	67	129	
Mean (StdDev)	2.96 (2.656)	7.32 (1.633)	5.55 (2.371)	5.11 (2.590)	
Median	2.32	7.75	5.62	5.21	
Min, Max	0.7, 6.5	4.0, 10.0	0.0, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Bone Pain Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	67	127	
Mean (StdDev)	2.95 (2.748)	6.67 (1.844)	4.92 (2.534)	4.38 (2.693)	
Median	2.36	7.14	5.21	4.00	
Min, Max	0.6, 6.5	3.8, 9.3	0.0, 10.0	0.0, 10.0	
C2D1 CFB					
n	4	10	67	125	
LS Mean (StdErr) [2]	-0.02 (0.460)	-0.54 (0.460)	-0.57 (0.169)	-0.72 (0.132)	
95% CI [2]	-1.04, 1.01	-1.56, 0.49	-0.90, -0.24	-0.98, -0.46	
Difference (95% CI) in CFB [2]		-0.52 (-1.82, 0.78)		-0.15 (-0.53, 0.22)	
p-value [3]		0.394		0.428	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Bone Pain Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	8	67	127	
Mean (StdDev)	2.64 (2.771)	6.60 (2.152)	4.79 (2.641)	4.15 (2.725)	
Median	2.15	6.68	5.27	3.57	
Min, Max	0.0, 6.3	3.9, 10.0	0.0, 10.0	0.0, 10.0	
C3D1 CFB					
n	4	8	67	125	
LS Mean (StdErr) [2]	-0.38 (0.675)	-0.75 (0.675)	-0.72 (0.199)	-0.96 (0.156)	
95% CI [2]	-1.94, 1.18	-2.30, 0.81	-1.11, -0.33	-1.27, -0.66	
Difference (95% CI) in CFB [2]		-0.37 (-2.36, 1.63)		-0.24 (-0.69, 0.20)	
p-value [3]		0.682		0.279	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Bone Pain Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	4	9	64	126	
Mean (StdDev)	2.74 (2.829)	5.92 (2.333)	4.82 (2.710)	4.17 (2.828)	
Median	2.25	4.86	4.63	3.52	
Min, Max	0.1, 6.4	3.4, 9.8	0.0, 9.8	0.0, 10.0	
C4D1 CFB					
n	4	9	64	124	
LS Mean (StdErr) [2]	-0.36 (0.790)	-1.27 (0.790)	-0.67 (0.238)	-0.85 (0.183)	
95% CI [2]	-2.15, 1.43	-3.05, 0.52	-1.14, -0.20	-1.21, -0.49	
Difference (95% CI) in CFB [2]		-0.91 (-3.19, 1.37)		-0.19 (-0.71, 0.34)	
p-value [3]		0.391		0.486	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Bone Pain Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	9	63	128	
Mean (StdDev)	2.74 (2.643)	5.27 (2.301)	4.82 (2.707)	3.97 (2.850)	
Median	2.31	4.50	4.71	3.44	
Min, Max	0.3, 6.1	2.5, 8.6	0.0, 9.8	0.0, 10.0	
C5D1 CFB					
n	4	9	63	126	
LS Mean (StdErr) [2]	-0.61 (0.853)	-2.18 (0.853)	-0.57 (0.252)	-0.93 (0.190)	
95% CI [2]	-2.54, 1.32	-4.11, -0.25	-1.06, -0.07	-1.30, -0.55	
Difference (95% CI) in CFB [2]		-1.57 (-4.03, 0.89)		-0.36 (-0.92, 0.19)	
p-value [3]		0.183		0.200	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Bone Pain Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	62	127	
Mean (StdDev)	2.86 (2.702)	5.44 (2.009)	4.77 (2.697)	3.81 (2.767)	
Median	2.54	6.00	5.00	3.43	
Min, Max	0.3, 6.1	2.1, 7.6	0.0, 9.6	0.0, 10.0	
C6D1 CFB					
n	4	9	62	125	
LS Mean (StdErr) [2]	-0.52 (0.832)	-2.13 (0.832)	-0.47 (0.262)	-1.04 (0.197)	
95% CI [2]	-2.40, 1.36	-4.01, -0.25	-0.98, 0.05	-1.43, -0.65	
Difference (95% CI) in CFB [2]		-1.60 (-4.00, 0.80)		-0.57 (-1.15, 0.01)	
p-value [3]		0.165		0.053	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Bone Pain Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	9	62	124	
Mean (StdDev)	2.66 (2.542)	5.09 (2.102)	4.74 (2.678)	3.77 (2.805)	
Median	2.28	3.64	5.12	3.19	
Min, Max	0.3, 5.8	2.8, 8.2	0.0, 9.4	0.0, 10.0	
C7D1 CFB					
n	4	9	62	122	
LS Mean (StdErr) [2]	-0.84 (0.716)	-2.65 (0.716)	-0.57 (0.270)	-1.06 (0.205)	
95% CI [2]	-2.46, 0.78	-4.27, -1.03	-1.11, -0.04	-1.46, -0.65	
Difference (95% CI) in CFB [2]		-1.80 (-3.87, 0.26)		-0.48 (-1.08, 0.11)	
Hedges'G (95% CI) in CFB		-0.85 (-2.42, 0.35)		-0.22 (-0.53, 0.09)	
p-value [3]		0.080		0.112	
					0.358

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Abdominal Pain Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	67	129	
Mean (StdDev)	2.32 (2.919)	5.80 (1.830)	4.08 (2.437)	3.73 (2.240)	
Median	1.36	5.93	4.14	3.38	
Min, Max	0.0, 6.6	2.9, 8.5	0.0, 9.6	0.0, 9.8	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Abdominal Pain Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	67	127	
Mean (StdDev)	2.36 (2.671)	4.79 (2.032)	3.29 (2.192)	3.03 (2.137)	
Median	1.54	5.29	3.36	2.71	
Min, Max	0.2, 6.1	0.4, 7.3	0.0, 8.9	0.0, 9.4	
C2D1 CFB					
n	4	10	67	125	
LS Mean (StdErr) [2]	0.34 (0.469)	-0.35 (0.469)	-0.73 (0.152)	-0.67 (0.119)	
95% CI [2]	-0.71, 1.38	-1.39, 0.70	-1.03, -0.44	-0.91, -0.44	
Difference (95% CI) in CFB [2]		-0.69 (-2.02, 0.64)		0.06 (-0.28, 0.40)	
p-value [3]		0.277		0.721	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Abdominal Pain Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	8	67	127	
Mean (StdDev)	1.86 (2.507)	3.97 (2.036)	3.13 (2.217)	2.70 (2.169)	
Median	0.89	4.32	3.00	2.36	
Min, Max	0.1, 5.6	0.3, 6.7	0.0, 8.4	0.0, 8.3	
C3D1 CFB					
n	4	8	67	125	
LS Mean (StdErr) [2]	-0.54 (0.351)	-1.47 (0.351)	-0.83 (0.194)	-0.96 (0.152)	
95% CI [2]	-1.35, 0.27	-2.28, -0.66	-1.22, -0.45	-1.26, -0.66	
Difference (95% CI) in CFB [2]		-0.93 (-1.97, 0.11)		-0.13 (-0.56, 0.31)	
p-value [3]		0.072		0.566	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Abdominal Pain Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	4	9	64	126	
Mean (StdDev)	1.66 (2.549)	3.41 (1.756)	3.10 (2.164)	2.46 (2.200)	
Median	0.59	3.14	3.15	2.00	
Min, Max	0.0, 5.5	0.1, 6.5	0.0, 7.9	0.0, 9.1	
C4D1 CFB					
n	4	9	64	124	
LS Mean (StdErr) [2]	-0.88 (0.551)	-2.52 (0.551)	-0.91 (0.231)	-1.17 (0.178)	
95% CI [2]	-2.13, 0.36	-3.77, -1.27	-1.37, -0.46	-1.52, -0.82	
Difference (95% CI) in CFB [2]		-1.64 (-3.23, -0.05)		-0.26 (-0.77, 0.25)	
p-value [3]		0.045		0.321	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Abdominal Pain Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	9	63	128	
Mean (StdDev)	1.69 (2.408)	2.79 (1.728)	3.19 (2.187)	2.40 (2.299)	
Median	0.76	2.91	3.00	1.80	
Min, Max	0.0, 5.2	0.0, 6.5	0.0, 8.1	0.0, 9.4	
C5D1 CFB					
n	4	9	63	126	
LS Mean (StdErr) [2]	-0.85 (0.718)	-3.10 (0.718)	-0.82 (0.251)	-1.22 (0.189)	
95% CI [2]	-2.47, 0.77	-4.72, -1.47	-1.31, -0.32	-1.60, -0.85	
Difference (95% CI) in CFB [2]		-2.24 (-4.31, -0.18)		-0.40 (-0.96, 0.15)	
p-value [3]		0.037		0.152	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Abdominal Pain Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	62	127	
Mean (StdDev)	1.65 (2.377)	2.59 (1.967)	2.66 (2.070)	2.25 (2.244)	
Median	0.64	2.79	2.46	1.71	
Min, Max	0.1, 5.2	0.0, 6.6	0.0, 7.1	0.0, 9.6	
C6D1 CFB					
n	4	9	62	125	
LS Mean (StdErr) [2]	-1.10 (0.906)	-3.63 (0.906)	-1.16 (0.252)	-1.31 (0.190)	
95% CI [2]	-3.15, 0.95	-5.67, -1.58	-1.66, -0.66	-1.68, -0.94	
Difference (95% CI) in CFB [2]		-2.53 (-5.14, 0.09)		-0.15 (-0.71, 0.41)	
p-value [3]		0.057		0.600	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Abdominal Pain Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	9	62	124	
Mean (StdDev)	1.92 (2.252)	3.13 (2.349)	2.83 (2.303)	2.26 (2.171)	
Median	1.15	3.00	2.45	1.78	
Min, Max	0.3, 5.1	0.0, 7.2	0.0, 8.3	0.0, 9.4	
C7D1 CFB					
n	4	9	62	122	
LS Mean (StdErr) [2]	-0.87 (1.072)	-3.31 (1.072)	-1.06 (0.247)	-1.31 (0.188)	
95% CI [2]	-3.29, 1.56	-5.74, -0.89	-1.55, -0.57	-1.68, -0.94	
Difference (95% CI) in CFB [2]		-2.45 (-5.54, 0.65)		-0.25 (-0.80, 0.29)	
Hedges'G (95% CI) in CFB		-0.77 (-2.32, 0.43)		-0.12 (-0.43, 0.18)	
p-value [3]		0.107		0.364	
					0.106

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Nausea Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	67	129	
Mean (StdDev)	2.16 (2.324)	3.65 (2.634)	3.43 (2.511)	2.89 (2.542)	
Median	1.07	2.77	3.00	2.36	
Min, Max	0.9, 5.6	0.0, 8.4	0.0, 8.9	0.0, 9.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Nausea Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	67	127	
Mean (StdDev)	1.95 (2.433)	3.42 (2.316)	2.92 (2.371)	2.49 (2.326)	
Median	1.11	3.61	2.42	2.00	
Min, Max	0.1, 5.5	0.0, 6.9	0.0, 8.3	0.0, 8.8	
C2D1 CFB					
n	4	10	67	125	
LS Mean (StdErr) [2]	-0.06 (0.590)	-0.02 (0.590)	-0.44 (0.165)	-0.36 (0.129)	
95% CI [2]	-1.38, 1.25	-1.33, 1.29	-0.76, -0.11	-0.61, -0.10	
Difference (95% CI) in CFB [2]		0.04 (-1.63, 1.71)		0.08 (-0.29, 0.44)	
p-value [3]		0.955		0.675	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Nausea Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	8	67	127	
Mean (StdDev)	1.70 (2.527)	2.67 (2.122)	2.58 (2.297)	2.27 (2.259)	
Median	0.65	2.57	2.00	1.57	
Min, Max	0.1, 5.4	0.0, 6.0	0.0, 7.7	0.0, 8.9	
C3D1 CFB					
n	4	8	67	125	
LS Mean (StdErr) [2]	-0.61 (0.715)	-0.73 (0.715)	-0.78 (0.198)	-0.60 (0.155)	
95% CI [2]	-2.26, 1.04	-2.38, 0.92	-1.17, -0.39	-0.90, -0.29	
Difference (95% CI) in CFB [2]		-0.11 (-2.22, 1.99)		0.18 (-0.25, 0.62)	
p-value [3]		0.903		0.409	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Nausea Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	4	9	64	126	
Mean (StdDev)	1.59 (2.643)	2.46 (1.895)	2.65 (2.224)	1.98 (2.237)	
Median	0.41	2.14	2.04	1.16	
Min, Max	0.0, 5.5	0.0, 6.6	0.0, 7.4	0.0, 9.2	
C4D1 CFB					
n	4	9	64	124	
LS Mean (StdErr) [2]	-0.96 (0.796)	-1.77 (0.796)	-0.81 (0.224)	-0.91 (0.173)	
95% CI [2]	-2.76, 0.84	-3.57, 0.03	-1.25, -0.37	-1.25, -0.57	
Difference (95% CI) in CFB [2]		-0.82 (-3.11, 1.48)		-0.10 (-0.60, 0.39)	
p-value [3]		0.442		0.676	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Nausea Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	9	63	128	
Mean (StdDev)	1.57 (2.410)	1.98 (1.757)	2.71 (2.220)	1.99 (2.246)	
Median	0.56	1.77	2.57	1.22	
Min, Max	0.0, 5.2	0.0, 5.7	0.0, 8.5	0.0, 8.9	
C5D1 CFB					
n	4	9	63	126	
LS Mean (StdErr) [2]	-1.04 (0.825)	-2.26 (0.825)	-0.75 (0.245)	-0.87 (0.184)	
95% CI [2]	-2.90, 0.83	-4.12, -0.39	-1.24, -0.27	-1.23, -0.50	
Difference (95% CI) in CFB [2]		-1.22 (-3.60, 1.16)		-0.11 (-0.65, 0.43)	
p-value [3]		0.276		0.682	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Nausea Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	62	127	
Mean (StdDev)	1.41 (2.495)	1.74 (1.668)	2.37 (2.105)	1.79 (2.171)	
Median	0.21	1.36	2.11	1.23	
Min, Max	0.1, 5.2	0.0, 5.4	0.0, 7.9	0.0, 9.9	
C6D1 CFB					
n	4	9	62	125	
LS Mean (StdErr) [2]	-1.40 (1.071)	-2.99 (1.071)	-1.05 (0.238)	-1.06 (0.179)	
95% CI [2]	-3.82, 1.02	-5.41, -0.57	-1.52, -0.58	-1.41, -0.70	
Difference (95% CI) in CFB [2]		-1.59 (-4.68, 1.49)		-0.01 (-0.53, 0.52)	
p-value [3]		0.273		0.978	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Nausea Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	9	62	124	
Mean (StdDev)	1.72 (2.352)	2.14 (2.060)	2.45 (2.285)	1.81 (2.145)	
Median	0.87	2.00	1.93	1.18	
Min, Max	0.0, 5.1	0.0, 6.3	0.0, 7.7	0.0, 9.5	
C7D1 CFB					
n	4	9	62	122	
LS Mean (StdErr) [2]	-0.96 (1.161)	-2.44 (1.161)	-0.96 (0.259)	-1.03 (0.197)	
95% CI [2]	-3.59, 1.67	-5.06, 0.19	-1.47, -0.45	-1.41, -0.64	
Difference (95% CI) in CFB [2]		-1.48 (-4.82, 1.87)		-0.06 (-0.64, 0.51)	
Hedges'G (95% CI) in CFB		-0.43 (-1.86, 0.81)		-0.03 (-0.34, 0.28)	
p-value [3]		0.345		0.827	
					0.590

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Spots Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	67	129	
Mean (StdDev)	6.61 (3.018)	6.08 (3.642)	5.72 (3.158)	5.23 (2.992)	
Median	7.61	5.96	6.21	5.43	
Min, Max	2.2, 9.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Spots Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	67	127	
Mean (StdDev)	6.57 (2.611)	5.61 (3.032)	5.32 (2.973)	4.35 (2.759)	
Median	7.36	6.00	5.57	4.21	
Min, Max	2.9, 8.7	0.0, 9.5	0.0, 10.0	0.0, 10.0	
C2D1 CFB					
n	4	10	67	125	
LS Mean (StdErr) [2]	-0.01 (0.736)	-0.23 (0.736)	-0.33 (0.165)	-0.87 (0.130)	
95% CI [2]	-1.65, 1.63	-1.87, 1.41	-0.66, -0.01	-1.13, -0.62	
Difference (95% CI) in CFB [2]		-0.23 (-2.31, 1.86)		-0.54 (-0.91, -0.18)	
p-value [3]		0.814		0.004	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Spots Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	8	67	127	
Mean (StdDev)	6.16 (2.733)	4.77 (3.116)	5.30 (3.012)	4.00 (2.616)	
Median	7.21	4.93	5.36	4.00	
Min, Max	2.2, 8.0	0.0, 8.9	0.0, 10.0	0.0, 9.8	
C3D1 CFB					
n	4	8	67	125	
LS Mean (StdErr) [2]	-0.07 (0.937)	-0.91 (0.937)	-0.29 (0.203)	-1.17 (0.159)	
95% CI [2]	-2.23, 2.10	-3.07, 1.25	-0.69, 0.11	-1.48, -0.85	
Difference (95% CI) in CFB [2]		-0.85 (-3.61, 1.92)		-0.88 (-1.33, -0.43)	
p-value [3]		0.501		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Spots Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	4	9	64	126	
Mean (StdDev)	6.25 (2.751)	4.37 (2.749)	5.19 (3.035)	3.80 (2.630)	
Median	7.39	3.57	5.23	3.65	
Min, Max	2.2, 8.0	0.0, 8.2	0.0, 10.0	0.0, 9.4	
C4D1 CFB					
n	4	9	64	124	
LS Mean (StdErr) [2]	0.09 (0.996)	-0.81 (0.996)	-0.24 (0.215)	-1.29 (0.165)	
95% CI [2]	-2.16, 2.35	-3.06, 1.44	-0.66, 0.19	-1.62, -0.96	
Difference (95% CI) in CFB [2]		-0.90 (-3.78, 1.97)		-1.05 (-1.53, -0.58)	
p-value [3]		0.495		<0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Spots Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	9	63	128	
Mean (StdDev)	5.92 (3.011)	4.34 (2.886)	5.07 (3.051)	3.59 (2.567)	
Median	7.04	3.27	5.07	3.07	
Min, Max	1.6, 8.0	0.6, 8.6	0.0, 10.0	0.0, 9.9	
C5D1 CFB					
n	4	9	63	126	
LS Mean (StdErr) [2]	-0.47 (1.121)	-1.11 (1.121)	-0.37 (0.232)	-1.52 (0.175)	
95% CI [2]	-3.01, 2.06	-3.64, 1.43	-0.83, 0.09	-1.86, -1.17	
Difference (95% CI) in CFB [2]		-0.63 (-3.87, 2.60)		-1.14 (-1.66, -0.63)	
p-value [3]		0.669		<0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Spots Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	62	127	
Mean (StdDev)	5.46 (3.126)	4.34 (2.603)	5.17 (3.065)	3.42 (2.586)	
Median	6.39	4.46	5.00	3.07	
Min, Max	1.1, 8.0	0.3, 8.0	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	4	9	62	125	
LS Mean (StdErr) [2]	-0.89 (1.267)	-1.15 (1.267)	-0.21 (0.269)	-1.57 (0.202)	
95% CI [2]	-3.76, 1.97	-4.02, 1.71	-0.74, 0.32	-1.97, -1.17	
Difference (95% CI) in CFB [2]		-0.26 (-3.92, 3.39)		-1.35 (-1.95, -0.76)	
p-value [3]		0.875		<0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Spots Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	9	62	124	
Mean (StdDev)	5.69 (2.968)	3.90 (2.898)	5.20 (3.001)	3.44 (2.655)	
Median	6.66	3.33	5.00	3.08	
Min, Max	1.4, 8.0	0.0, 8.1	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	4	9	62	122	
LS Mean (StdErr) [2]	-0.67 (1.115)	-1.58 (1.115)	-0.33 (0.275)	-1.61 (0.209)	
95% CI [2]	-3.19, 1.85	-4.10, 0.94	-0.87, 0.21	-2.02, -1.19	
Difference (95% CI) in CFB [2]		-0.91 (-4.13, 2.31)		-1.28 (-1.89, -0.67)	
Hedges'G (95% CI) in CFB		-0.27 (-1.67, 0.99)		-0.56 (-0.88, -0.26)	
p-value [3]		0.538		<0.0001	
					0.864

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Itching Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	67	129	
Mean (StdDev)	6.05 (3.098)	7.35 (2.389)	5.69 (2.795)	4.96 (2.767)	
Median	6.75	7.43	6.15	5.00	
Min, Max	1.7, 9.0	3.3, 10.0	0.0, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Itching Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	67	127	
Mean (StdDev)	6.00 (2.834)	6.19 (1.645)	5.02 (2.814)	3.93 (2.479)	
Median	6.43	6.89	5.31	4.00	
Min, Max	2.2, 8.9	3.3, 8.6	0.0, 10.0	0.0, 9.9	
C2D1 CFB					
n	4	10	67	125	
LS Mean (StdErr) [2]	-0.15 (0.830)	-0.97 (0.830)	-0.69 (0.214)	-1.10 (0.168)	
95% CI [2]	-2.00, 1.70	-2.82, 0.88	-1.11, -0.27	-1.44, -0.77	
Difference (95% CI) in CFB [2]		-0.82 (-3.18, 1.53)		-0.42 (-0.89, 0.06)	
p-value [3]		0.454		0.084	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Itching Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	8	67	127	
Mean (StdDev)	5.12 (2.482)	5.10 (1.672)	4.76 (2.851)	3.39 (2.500)	
Median	5.78	4.75	4.77	3.07	
Min, Max	1.6, 7.4	3.0, 8.0	0.0, 10.0	0.0, 9.7	
C3D1 CFB					
n	4	8	67	125	
LS Mean (StdErr) [2]	-0.79 (1.413)	-2.10 (1.413)	-0.86 (0.257)	-1.56 (0.201)	
95% CI [2]	-4.05, 2.47	-5.35, 1.16	-1.36, -0.35	-1.96, -1.16	
Difference (95% CI) in CFB [2]		-1.31 (-5.47, 2.86)		-0.71 (-1.28, -0.14)	
p-value [3]		0.491		0.016	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Itching Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	4	9	64	126	
Mean (StdDev)	5.19 (2.582)	4.05 (2.276)	4.65 (2.906)	3.22 (2.597)	
Median	6.01	3.79	4.93	2.75	
Min, Max	1.4, 7.3	0.0, 8.0	0.0, 10.0	0.0, 10.0	
C4D1 CFB					
n	4	9	64	124	
LS Mean (StdErr) [2]	-0.78 (1.800)	-2.72 (1.800)	-1.02 (0.295)	-1.77 (0.227)	
95% CI [2]	-4.85, 3.30	-6.79, 1.35	-1.61, -0.44	-2.22, -1.32	
Difference (95% CI) in CFB [2]		-1.95 (-7.14, 3.25)		-0.75 (-1.40, -0.10)	
p-value [3]		0.419		0.025	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Itching Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	9	63	128	
Mean (StdDev)	4.84 (3.022)	3.82 (2.552)	4.76 (2.780)	2.99 (2.524)	
Median	5.56	3.57	4.69	2.72	
Min, Max	0.8, 7.5	0.0, 7.5	0.0, 10.0	0.0, 10.0	
C5D1 CFB					
n	4	9	63	126	
LS Mean (StdErr) [2]	-1.64 (1.911)	-3.70 (1.911)	-0.84 (0.305)	-1.89 (0.230)	
95% CI [2]	-5.96, 2.69	-8.03, 0.62	-1.44, -0.24	-2.35, -1.44	
Difference (95% CI) in CFB [2]		-2.07 (-7.58, 3.44)		-1.05 (-1.72, -0.38)	
p-value [3]		0.418		0.002	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Itching Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	62	127	
Mean (StdDev)	4.49 (3.034)	3.25 (2.441)	4.73 (2.760)	2.99 (2.541)	
Median	5.07	2.93	4.76	2.57	
Min, Max	0.4, 7.5	0.0, 6.9	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	4	9	62	125	
LS Mean (StdErr) [2]	-1.97 (1.789)	-4.29 (1.789)	-0.87 (0.315)	-1.94 (0.237)	
95% CI [2]	-6.02, 2.08	-8.34, -0.24	-1.50, -0.25	-2.40, -1.47	
Difference (95% CI) in CFB [2]		-2.32 (-7.48, 2.84)		-1.06 (-1.76, -0.37)	
p-value [3]		0.335		0.003	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Itching Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	9	62	124	
Mean (StdDev)	5.01 (2.980)	3.26 (2.228)	4.82 (2.651)	2.96 (2.538)	
Median	5.81	3.55	4.80	2.64	
Min, Max	0.9, 7.6	0.0, 6.6	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	4	9	62	122	
LS Mean (StdErr) [2]	-1.39 (1.711)	-4.10 (1.711)	-0.87 (0.327)	-1.97 (0.249)	
95% CI [2]	-5.26, 2.48	-7.97, -0.23	-1.52, -0.23	-2.46, -1.48	
Difference (95% CI) in CFB [2]		-2.71 (-7.64, 2.23)		-1.09 (-1.82, -0.37)	
Hedges'G (95% CI) in CFB		-0.53 (-2.00, 0.69)		-0.41 (-0.72, -0.10)	
p-value [3]		0.246		0.003	
					0.291

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Flushing Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	67	129	
Mean (StdDev)	5.50 (2.650)	6.10 (2.862)	5.73 (2.678)	4.99 (2.494)	
Median	5.07	6.46	5.57	5.14	
Min, Max	2.9, 9.0	0.0, 9.9	0.0, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Flushing Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	67	127	
Mean (StdDev)	5.41 (2.618)	4.77 (2.532)	5.15 (2.745)	4.35 (2.533)	
Median	5.04	4.86	4.86	4.29	
Min, Max	2.7, 8.9	0.0, 8.2	0.0, 10.0	0.0, 10.0	
C2D1 CFB					
n	4	10	67	125	
LS Mean (StdErr) [2]	-0.23 (0.703)	-1.32 (0.703)	-0.57 (0.198)	-0.67 (0.156)	
95% CI [2]	-1.80, 1.34	-2.89, 0.24	-0.96, -0.18	-0.98, -0.37	
Difference (95% CI) in CFB [2]		-1.09 (-3.09, 0.90)		-0.10 (-0.54, 0.34)	
p-value [3]		0.249		0.649	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Flushing Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	8	67	127	
Mean (StdDev)	4.91 (2.196)	4.38 (2.534)	4.98 (2.916)	3.89 (2.493)	
Median	5.25	4.25	5.00	3.79	
Min, Max	2.0, 7.2	0.6, 8.0	0.0, 10.0	0.0, 10.0	
C3D1 CFB					
n	4	8	67	125	
LS Mean (StdErr) [2]	-0.52 (1.110)	-1.79 (1.110)	-0.66 (0.235)	-1.06 (0.185)	
95% CI [2]	-3.08, 2.04	-4.35, 0.77	-1.12, -0.20	-1.42, -0.70	
Difference (95% CI) in CFB [2]		-1.27 (-4.55, 2.00)		-0.40 (-0.92, 0.12)	
p-value [3]		0.396		0.133	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Flushing Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	4	9	64	126	
Mean (StdDev)	4.75 (2.840)	3.57 (2.528)	4.99 (2.911)	3.72 (2.528)	
Median	4.78	3.46	4.46	3.60	
Min, Max	1.4, 8.0	0.0, 8.0	0.0, 10.0	0.0, 10.0	
C4D1 CFB					
n	4	9	64	124	
LS Mean (StdErr) [2]	-0.93 (0.986)	-2.70 (0.986)	-0.68 (0.273)	-1.26 (0.210)	
95% CI [2]	-3.16, 1.30	-4.93, -0.47	-1.22, -0.15	-1.67, -0.84	
Difference (95% CI) in CFB [2]		-1.77 (-4.62, 1.07)		-0.57 (-1.17, 0.03)	
p-value [3]		0.192		0.063	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Flushing Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	9	63	128	
Mean (StdDev)	4.50 (3.042)	3.12 (2.506)	4.99 (2.940)	3.62 (2.514)	
Median	4.49	2.38	4.71	3.59	
Min, Max	1.0, 8.0	0.2, 7.2	0.0, 10.0	0.0, 9.8	
C5D1 CFB					
n	4	9	63	126	
LS Mean (StdErr) [2]	-1.47 (1.142)	-3.49 (1.142)	-0.72 (0.302)	-1.39 (0.228)	
95% CI [2]	-4.05, 1.11	-6.07, -0.91	-1.32, -0.12	-1.84, -0.94	
Difference (95% CI) in CFB [2]		-2.02 (-5.32, 1.27)		-0.67 (-1.34, -0.01)	
p-value [3]		0.198		0.048	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Flushing Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	62	127	
Mean (StdDev)	3.91 (3.057)	2.78 (2.305)	4.90 (2.943)	3.48 (2.542)	
Median	4.01	3.07	4.86	3.25	
Min, Max	0.3, 7.4	0.0, 6.6	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	4	9	62	125	
LS Mean (StdErr) [2]	-2.11 (1.149)	-3.94 (1.149)	-0.81 (0.309)	-1.50 (0.232)	
95% CI [2]	-4.71, 0.49	-6.54, -1.34	-1.42, -0.20	-1.96, -1.04	
Difference (95% CI) in CFB [2]		-1.83 (-5.15, 1.48)		-0.69 (-1.37, -0.01)	
p-value [3]		0.242		0.047	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Flushing Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	9	62	124	
Mean (StdDev)	4.13 (2.923)	2.93 (2.602)	4.96 (2.891)	3.28 (2.485)	
Median	4.36	3.23	4.64	2.77	
Min, Max	0.4, 7.4	0.0, 7.0	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	4	9	62	122	
LS Mean (StdErr) [2]	-1.90 (1.317)	-3.89 (1.317)	-0.74 (0.318)	-1.56 (0.242)	
95% CI [2]	-4.87, 1.08	-6.87, -0.91	-1.37, -0.12	-2.03, -1.08	
Difference (95% CI) in CFB [2]		-1.99 (-5.79, 1.81)		-0.81 (-1.52, -0.11)	
Hedges'G (95% CI) in CFB		-0.51 (-1.97, 0.72)		-0.31 (-0.62, -0.00)	
p-value [3]		0.266		0.024	
					0.532

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Fatigue Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	67	129	
Mean (StdDev)	6.39 (2.227)	7.45 (1.903)	6.73 (2.016)	6.59 (2.130)	
Median	6.93	8.05	6.64	6.77	
Min, Max	3.3, 8.4	3.5, 10.0	0.0, 10.0	0.1, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Fatigue Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	67	127	
Mean (StdDev)	5.96 (1.708)	6.78 (2.450)	6.32 (2.002)	5.90 (2.298)	
Median	6.14	7.04	6.31	6.07	
Min, Max	3.7, 7.9	1.0, 10.0	2.3, 10.0	0.1, 10.0	
C2D1 CFB					
n	4	10	67	125	
LS Mean (StdErr) [2]	-0.61 (0.397)	-0.73 (0.397)	-0.44 (0.166)	-0.73 (0.130)	
95% CI [2]	-1.50, 0.27	-1.61, 0.16	-0.77, -0.11	-0.99, -0.48	
Difference (95% CI) in CFB [2]		-0.12 (-1.24, 1.01)		-0.29 (-0.66, 0.08)	
p-value [3]		0.822		0.120	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Fatigue Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	8	67	127	
Mean (StdDev)	6.43 (1.841)	5.95 (2.507)	5.89 (2.363)	5.53 (2.348)	
Median	6.64	5.57	5.86	5.64	
Min, Max	4.1, 8.4	1.8, 10.0	0.3, 10.0	0.2, 10.0	
C3D1 CFB					
n	4	8	67	125	
LS Mean (StdErr) [2]	0.03 (0.446)	-0.98 (0.446)	-0.88 (0.213)	-1.12 (0.167)	
95% CI [2]	-1.00, 1.06	-2.01, 0.04	-1.30, -0.46	-1.44, -0.79	
Difference (95% CI) in CFB [2]		-1.01 (-2.33, 0.30)		-0.24 (-0.71, 0.24)	
p-value [3]		0.114		0.327	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Fatigue Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	4	9	64	126	
Mean (StdDev)	5.52 (1.287)	5.32 (2.525)	5.69 (2.500)	5.27 (2.494)	
Median	5.58	4.79	5.88	5.32	
Min, Max	4.0, 6.9	1.1, 10.0	0.2, 10.0	0.0, 10.0	
C4D1 CFB					
n	4	9	64	124	
LS Mean (StdErr) [2]	-1.28 (0.537)	-2.40 (0.537)	-1.05 (0.262)	-1.36 (0.202)	
95% CI [2]	-2.49, -0.06	-3.61, -1.18	-1.56, -0.53	-1.76, -0.96	
Difference (95% CI) in CFB [2]		-1.12 (-2.67, 0.43)		-0.32 (-0.89, 0.26)	
p-value [3]		0.137		0.283	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Fatigue Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	9	63	128	
Mean (StdDev)	4.48 (1.173)	5.20 (2.415)	5.63 (2.485)	5.23 (2.485)	
Median	4.38	5.00	5.57	5.37	
Min, Max	3.1, 6.0	1.4, 10.0	0.6, 10.0	0.0, 10.0	
C5D1 CFB					
n	4	9	63	126	
LS Mean (StdErr) [2]	-2.50 (0.785)	-2.80 (0.785)	-1.02 (0.268)	-1.30 (0.202)	
95% CI [2]	-4.28, -0.73	-4.58, -1.02	-1.55, -0.49	-1.70, -0.90	
Difference (95% CI) in CFB [2]		-0.30 (-2.56, 1.97)		-0.28 (-0.87, 0.31)	
p-value [3]		0.773		0.347	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Fatigue Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	62	127	
Mean (StdDev)	4.41 (1.068)	5.17 (2.908)	5.69 (2.488)	5.00 (2.640)	
Median	3.93	5.00	5.80	5.08	
Min, Max	3.8, 6.0	0.0, 10.0	0.4, 10.0	0.0, 10.0	
C6D1 CFB					
n	4	9	62	125	
LS Mean (StdErr) [2]	-2.61 (0.877)	-3.03 (0.877)	-0.89 (0.291)	-1.48 (0.219)	
95% CI [2]	-4.60, -0.63	-5.02, -1.05	-1.47, -0.32	-1.92, -1.05	
Difference (95% CI) in CFB [2]		-0.42 (-2.95, 2.11)		-0.59 (-1.24, 0.05)	
p-value [3]		0.715		0.070	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Fatigue Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	9	62	124	
Mean (StdDev)	4.36 (0.967)	4.94 (2.938)	5.66 (2.566)	4.88 (2.566)	
Median	4.00	4.86	5.61	5.07	
Min, Max	3.6, 5.8	0.0, 10.0	0.2, 10.0	0.0, 10.0	
C7D1 CFB					
n	4	9	62	122	
LS Mean (StdErr) [2]	-2.74 (0.979)	-3.32 (0.979)	-0.92 (0.294)	-1.57 (0.223)	
95% CI [2]	-4.96, -0.52	-5.53, -1.10	-1.50, -0.34	-2.01, -1.13	
Difference (95% CI) in CFB [2]		-0.58 (-3.40, 2.25)		-0.66 (-1.31, -0.01)	
Hedges'G (95% CI) in CFB		-0.20 (-1.57, 1.08)		-0.27 (-0.58, 0.03)	
p-value [3]		0.655		0.047	
					0.690

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Dizziness Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	67	129	
Mean (StdDev)	3.30 (3.065)	4.01 (2.824)	3.59 (2.768)	3.61 (2.881)	
Median	3.50	4.09	2.86	3.50	
Min, Max	0.1, 6.1	0.0, 8.2	0.0, 9.3	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Dizziness Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	67	127	
Mean (StdDev)	2.38 (2.725)	3.61 (2.623)	3.16 (2.654)	3.05 (2.673)	
Median	1.79	3.47	2.79	2.58	
Min, Max	0.0, 5.9	0.0, 8.3	0.0, 8.7	0.0, 10.0	
C2D1 CFB					
n	4	10	67	125	
LS Mean (StdErr) [2]	-0.89 (0.665)	-0.01 (0.665)	-0.38 (0.182)	-0.57 (0.143)	
95% CI [2]	-2.37, 0.59	-1.49, 1.47	-0.73, -0.02	-0.85, -0.29	
Difference (95% CI) in CFB [2]		0.88 (-1.00, 2.76)		-0.20 (-0.60, 0.21)	
p-value [3]		0.322		0.340	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Dizziness Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	8	67	127	
Mean (StdDev)	3.02 (3.491)	3.08 (2.841)	2.75 (2.529)	2.74 (2.663)	
Median	2.89	2.46	2.07	2.14	
Min, Max	0.0, 6.3	0.0, 7.9	0.0, 8.1	0.0, 10.0	
C3D1 CFB					
n	4	8	67	125	
LS Mean (StdErr) [2]	-0.22 (0.825)	-0.80 (0.825)	-0.75 (0.213)	-0.87 (0.167)	
95% CI [2]	-2.12, 1.69	-2.71, 1.10	-1.17, -0.33	-1.20, -0.54	
Difference (95% CI) in CFB [2]		-0.59 (-3.02, 1.85)		-0.11 (-0.59, 0.36)	
p-value [3]		0.594		0.633	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Dizziness Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	4	9	64	126	
Mean (StdDev)	2.53 (3.238)	2.76 (2.480)	2.93 (2.630)	2.67 (2.730)	
Median	1.68	2.54	2.39	1.92	
Min, Max	0.0, 6.8	0.0, 7.5	0.0, 9.9	0.0, 10.0	
C4D1 CFB					
n	4	9	64	124	
LS Mean (StdErr) [2]	-1.04 (1.008)	-1.43 (1.008)	-0.60 (0.255)	-0.96 (0.196)	
95% CI [2]	-3.32, 1.24	-3.71, 0.85	-1.10, -0.09	-1.35, -0.57	
Difference (95% CI) in CFB [2]		-0.39 (-3.30, 2.52)		-0.37 (-0.93, 0.20)	
p-value [3]		0.769		0.202	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Dizziness Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	9	63	128	
Mean (StdDev)	2.13 (3.084)	2.55 (2.615)	2.98 (2.582)	2.54 (2.639)	
Median	1.00	1.69	2.36	1.80	
Min, Max	0.0, 6.5	0.0, 7.8	0.0, 9.6	0.0, 10.0	
C5D1 CFB					
n	4	9	63	126	
LS Mean (StdErr) [2]	-1.73 (0.962)	-1.97 (0.962)	-0.46 (0.251)	-0.97 (0.189)	
95% CI [2]	-3.90, 0.45	-4.15, 0.20	-0.96, 0.03	-1.35, -0.60	
Difference (95% CI) in CFB [2]		-0.25 (-3.02, 2.53)		-0.51 (-1.06, 0.04)	
p-value [3]		0.845		0.072	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Dizziness Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	62	127	
Mean (StdDev)	2.04 (3.054)	2.15 (2.341)	2.74 (2.584)	2.32 (2.537)	
Median	0.86	1.79	1.79	1.58	
Min, Max	0.0, 6.5	0.0, 7.1	0.0, 8.6	0.0, 10.0	
C6D1 CFB					
n	4	9	62	125	
LS Mean (StdErr) [2]	-1.80 (1.244)	-2.19 (1.244)	-0.74 (0.266)	-1.20 (0.200)	
95% CI [2]	-4.61, 1.01	-5.01, 0.62	-1.26, -0.21	-1.60, -0.80	
Difference (95% CI) in CFB [2]		-0.39 (-3.98, 3.20)		-0.46 (-1.05, 0.13)	
p-value [3]		0.810		0.124	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Dizziness Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	9	62	124	
Mean (StdDev)	1.96 (2.865)	2.22 (2.402)	2.77 (2.641)	2.33 (2.562)	
Median	0.89	1.36	1.96	1.62	
Min, Max	0.0, 6.1	0.0, 7.5	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	4	9	62	122	
LS Mean (StdErr) [2]	-1.80 (1.343)	-1.72 (1.343)	-0.74 (0.275)	-1.17 (0.209)	
95% CI [2]	-4.84, 1.24	-4.75, 1.32	-1.28, -0.20	-1.59, -0.76	
Difference (95% CI) in CFB [2]		0.08 (-3.79, 3.95)		-0.43 (-1.04, 0.18)	
Hedges'G (95% CI) in CFB		0.02 (-1.30, 1.35)		-0.19 (-0.50, 0.12)	
p-value [3]		0.963		0.163	
					0.744

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Brain Fog Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	67	129	
Mean (StdDev)	3.54 (4.142)	6.00 (3.151)	5.12 (2.657)	5.33 (2.455)	
Median	3.11	6.46	5.08	5.36	
Min, Max	0.0, 7.9	0.0, 10.0	0.0, 10.0	0.0, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Brain Fog Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	67	127	
Mean (StdDev)	3.14 (3.591)	5.70 (3.263)	4.62 (2.609)	4.66 (2.632)	
Median	3.07	6.54	4.21	4.50	
Min, Max	0.0, 6.4	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C2D1 CFB					
n	4	10	67	125	
LS Mean (StdErr) [2]	-0.75 (0.342)	-0.73 (0.342)	-0.45 (0.157)	-0.65 (0.123)	
95% CI [2]	-1.52, 0.01	-1.49, 0.03	-0.76, -0.14	-0.90, -0.41	
Difference (95% CI) in CFB [2]		0.02 (-0.95, 0.99)		-0.21 (-0.56, 0.14)	
p-value [3]		0.962		0.246	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Brain Fog Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	8	67	127	
Mean (StdDev)	3.39 (3.970)	5.88 (3.075)	4.36 (2.667)	4.32 (2.685)	
Median	3.00	6.07	3.93	4.00	
Min, Max	0.0, 7.6	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C3D1 CFB					
n	4	8	67	125	
LS Mean (StdErr) [2]	-0.42 (0.638)	-0.83 (0.638)	-0.71 (0.186)	-1.01 (0.146)	
95% CI [2]	-1.89, 1.05	-2.30, 0.64	-1.08, -0.34	-1.30, -0.72	
Difference (95% CI) in CFB [2]		-0.42 (-2.30, 1.46)		-0.30 (-0.72, 0.11)	
p-value [3]		0.623		0.153	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Brain Fog Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	4	9	64	126	
Mean (StdDev)	2.75 (3.128)	4.46 (3.324)	4.18 (2.774)	4.16 (2.812)	
Median	2.50	3.86	3.89	3.88	
Min, Max	0.0, 6.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C4D1 CFB					
n	4	9	64	124	
LS Mean (StdErr) [2]	-1.49 (0.819)	-2.09 (0.819)	-0.86 (0.231)	-1.15 (0.177)	
95% CI [2]	-3.34, 0.36	-3.94, -0.24	-1.31, -0.40	-1.50, -0.80	
Difference (95% CI) in CFB [2]		-0.60 (-2.96, 1.76)		-0.29 (-0.80, 0.22)	
p-value [3]		0.580		0.265	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Brain Fog Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	9	63	128	
Mean (StdDev)	2.32 (2.854)	4.25 (3.296)	4.01 (2.775)	4.16 (2.832)	
Median	1.71	4.00	3.50	4.45	
Min, Max	0.0, 5.8	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C5D1 CFB					
n	4	9	63	126	
LS Mean (StdErr) [2]	-2.21 (0.753)	-2.59 (0.753)	-0.90 (0.248)	-1.02 (0.187)	
95% CI [2]	-3.91, -0.50	-4.30, -0.89	-1.39, -0.41	-1.39, -0.65	
Difference (95% CI) in CFB [2]		-0.39 (-2.56, 1.79)		-0.12 (-0.67, 0.42)	
p-value [3]		0.696		0.653	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Brain Fog Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	62	127	
Mean (StdDev)	2.50 (3.000)	4.09 (3.279)	4.06 (2.742)	3.99 (2.869)	
Median	2.00	4.57	3.64	3.36	
Min, Max	0.0, 6.0	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C6D1 CFB					
n	4	9	62	125	
LS Mean (StdErr) [2]	-2.14 (0.828)	-2.99 (0.828)	-0.78 (0.243)	-1.19 (0.183)	
95% CI [2]	-4.01, -0.26	-4.87, -1.12	-1.26, -0.30	-1.55, -0.83	
Difference (95% CI) in CFB [2]		-0.85 (-3.24, 1.53)		-0.41 (-0.94, 0.13)	
p-value [3]		0.439		0.138	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Brain Fog Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	9	62	124	
Mean (StdDev)	2.50 (2.957)	4.01 (3.304)	4.10 (2.848)	3.92 (2.908)	
Median	2.11	4.36	3.64	3.61	
Min, Max	0.0, 5.8	0.0, 10.0	0.0, 10.0	0.0, 10.0	
C7D1 CFB					
n	4	9	62	122	
LS Mean (StdErr) [2]	-2.10 (0.865)	-3.00 (0.865)	-0.79 (0.256)	-1.24 (0.195)	
95% CI [2]	-4.05, -0.14	-4.95, -1.04	-1.30, -0.29	-1.63, -0.86	
Difference (95% CI) in CFB [2]		-0.90 (-3.39, 1.60)		-0.45 (-1.02, 0.12)	
Hedges'G (95% CI) in CFB		-0.35 (-1.76, 0.90)		-0.21 (-0.52, 0.09)	
p-value [3]		0.437		0.121	
					0.984

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Headache Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	67	129	
Mean (StdDev)	3.39 (2.532)	5.59 (2.328)	4.14 (2.733)	3.90 (2.540)	
Median	3.21	4.99	4.36	3.85	
Min, Max	1.0, 6.1	2.2, 8.4	0.0, 9.9	0.0, 9.9	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Headache Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	67	127	
Mean (StdDev)	2.41 (2.716)	5.10 (2.097)	3.86 (2.585)	3.34 (2.419)	
Median	1.50	5.11	3.79	3.00	
Min, Max	0.4, 6.3	1.9, 7.6	0.0, 9.1	0.0, 10.0	
C2D1 CFB					
n	4	10	67	125	
LS Mean (StdErr) [2]	-1.40 (0.255)	-1.18 (0.255)	-0.25 (0.169)	-0.55 (0.133)	
95% CI [2]	-1.97, -0.83	-1.75, -0.61	-0.58, 0.09	-0.81, -0.29	
Difference (95% CI) in CFB [2]		0.22 (-0.51, 0.94)		-0.30 (-0.68, 0.07)	
p-value [3]		0.520		0.113	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Headache Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	8	67	127	
Mean (StdDev)	1.97 (2.658)	5.25 (2.172)	3.50 (2.556)	3.02 (2.359)	
Median	0.82	5.32	3.08	2.50	
Min, Max	0.3, 5.9	2.5, 8.3	0.0, 9.1	0.0, 10.0	
C3D1 CFB					
n	4	8	67	125	
LS Mean (StdErr) [2]	-1.88 (0.472)	-0.91 (0.472)	-0.57 (0.216)	-0.85 (0.170)	
95% CI [2]	-2.97, -0.79	-1.99, 0.18	-0.99, -0.14	-1.18, -0.51	
Difference (95% CI) in CFB [2]		0.97 (-0.42, 2.36)		-0.28 (-0.76, 0.20)	
p-value [3]		0.146		0.251	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Headache Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	4	9	64	126	
Mean (StdDev)	1.42 (2.648)	4.45 (1.928)	3.60 (2.443)	2.89 (2.379)	
Median	0.14	3.79	3.22	2.48	
Min, Max	0.0, 5.4	2.1, 7.4	0.0, 8.4	0.0, 9.9	
C4D1 CFB					
n	4	9	64	124	
LS Mean (StdErr) [2]	-2.79 (0.344)	-2.35 (0.344)	-0.53 (0.239)	-1.00 (0.184)	
95% CI [2]	-3.57, -2.02	-3.13, -1.58	-1.00, -0.06	-1.36, -0.63	
Difference (95% CI) in CFB [2]		0.44 (-0.55, 1.43)		-0.47 (-0.99, 0.06)	
p-value [3]		0.341		0.083	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Headache Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	9	63	128	
Mean (StdDev)	1.72 (2.489)	3.59 (1.627)	3.53 (2.461)	2.85 (2.411)	
Median	0.79	3.64	2.92	2.37	
Min, Max	0.0, 5.3	1.7, 6.8	0.0, 9.1	0.0, 10.0	
C5D1 CFB					
n	4	9	63	126	
LS Mean (StdErr) [2]	-2.30 (0.460)	-2.87 (0.460)	-0.69 (0.241)	-1.09 (0.182)	
95% CI [2]	-3.34, -1.26	-3.91, -1.83	-1.17, -0.22	-1.45, -0.73	
Difference (95% CI) in CFB [2]		-0.57 (-1.89, 0.76)		-0.40 (-0.93, 0.13)	
p-value [3]		0.360		0.139	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Headache Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	62	127	
Mean (StdDev)	1.47 (2.620)	3.25 (1.603)	3.24 (2.457)	2.64 (2.452)	
Median	0.25	2.71	2.79	2.00	
Min, Max	0.0, 5.4	1.6, 6.2	0.0, 8.9	0.0, 10.0	
C6D1 CFB					
n	4	9	62	125	
LS Mean (StdErr) [2]	-2.92 (0.409)	-3.71 (0.409)	-0.82 (0.245)	-1.23 (0.185)	
95% CI [2]	-3.84, -1.99	-4.63, -2.78	-1.30, -0.33	-1.60, -0.87	
Difference (95% CI) in CFB [2]		-0.79 (-1.97, 0.39)		-0.42 (-0.96, 0.13)	
p-value [3]		0.163		0.132	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Headache Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	9	62	124	
Mean (StdDev)	1.48 (2.386)	3.73 (1.687)	3.33 (2.573)	2.58 (2.393)	
Median	0.46	3.09	2.86	1.84	
Min, Max	0.0, 5.0	1.9, 7.2	0.0, 8.9	0.0, 10.0	
C7D1 CFB					
n	4	9	62	122	
LS Mean (StdErr) [2]	-2.71 (0.522)	-2.93 (0.522)	-0.73 (0.250)	-1.26 (0.190)	
95% CI [2]	-3.89, -1.53	-4.11, -1.75	-1.23, -0.24	-1.63, -0.88	
Difference (95% CI) in CFB [2]		-0.22 (-1.72, 1.29)		-0.53 (-1.08, 0.03)	
Hedges'G (95% CI) in CFB		-0.14 (-1.50, 1.15)		-0.25 (-0.57, 0.05)	
p-value [3]		0.752		0.063	
					0.514

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Count

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	67	129	
Mean (StdDev)	0.84 (0.710)	1.87 (1.459)	1.53 (1.502)	1.41 (1.660)	
Median	0.86	1.57	1.15	0.93	
Min, Max	0.0, 1.6	0.0, 4.6	0.0, 7.2	0.0, 12.2	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Count	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	67	127	
Mean (StdDev)	0.50 (0.274)	1.56 (1.267)	1.28 (1.299)	1.06 (1.422)	
Median	0.57	1.39	0.64	0.64	
Min, Max	0.1, 0.7	0.0, 3.7	0.0, 4.9	0.0, 10.7	
C2D1 CFB					
n	4	10	67	125	
LS Mean (StdErr) [2]	-0.30 (0.511)	-0.22 (0.511)	-0.33 (0.111)	-0.44 (0.087)	
95% CI [2]	-1.44, 0.84	-1.35, 0.92	-0.55, -0.11	-0.62, -0.27	
Difference (95% CI) in CFB [2]		0.08 (-1.36, 1.53)		-0.11 (-0.36, 0.13)	
p-value [3]		0.899		0.372	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Count	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	8	67	127	
Mean (StdDev)	0.53 (0.540)	0.76 (0.915)	1.17 (1.184)	1.00 (1.198)	
Median	0.45	0.29	0.71	0.67	
Min, Max	0.0, 1.2	0.0, 2.3	0.0, 4.4	0.0, 5.8	
C3D1 CFB					
n	4	8	67	125	
LS Mean (StdErr) [2]	-0.37 (0.593)	-1.13 (0.593)	-0.47 (0.145)	-0.54 (0.114)	
95% CI [2]	-1.73, 1.00	-2.50, 0.24	-0.76, -0.18	-0.76, -0.31	
Difference (95% CI) in CFB [2]		-0.77 (-2.52, 0.98)		-0.07 (-0.39, 0.25)	
p-value [3]		0.342		0.678	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Count	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	4	9	64	126	
Mean (StdDev)	0.44 (0.430)	0.82 (0.907)	1.16 (1.152)	1.00 (1.393)	
Median	0.46	0.57	0.73	0.46	
Min, Max	0.0, 0.8	0.0, 2.8	0.0, 4.8	0.0, 9.0	
C4D1 CFB					
n	4	9	64	124	
LS Mean (StdErr) [2]	-0.55 (0.532)	-1.19 (0.532)	-0.49 (0.142)	-0.50 (0.109)	
95% CI [2]	-1.75, 0.66	-2.39, 0.02	-0.77, -0.21	-0.72, -0.29	
Difference (95% CI) in CFB [2]		-0.64 (-2.17, 0.90)		-0.02 (-0.33, 0.30)	
p-value [3]		0.371		0.924	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Count	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	9	63	128	
Mean (StdDev)	0.34 (0.240)	0.78 (0.670)	1.19 (1.206)	1.01 (1.475)	
Median	0.38	0.82	0.77	0.50	
Min, Max	0.0, 0.6	0.0, 1.9	0.0, 4.8	0.0, 9.6	
C5D1 CFB					
n	4	9	63	126	
LS Mean (StdErr) [2]	-0.57 (0.542)	-1.04 (0.542)	-0.48 (0.163)	-0.54 (0.123)	
95% CI [2]	-1.80, 0.65	-2.27, 0.18	-0.80, -0.16	-0.78, -0.30	
Difference (95% CI) in CFB [2]		-0.47 (-2.04, 1.09)		-0.06 (-0.42, 0.30)	
p-value [3]		0.511		0.737	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Count	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	62	127	
Mean (StdDev)	0.31 (0.226)	0.80 (0.870)	1.10 (1.293)	0.92 (1.308)	
Median	0.36	0.50	0.65	0.43	
Min, Max	0.0, 0.5	0.0, 2.3	0.0, 6.5	0.0, 9.0	
C6D1 CFB					
n	4	9	62	125	
LS Mean (StdErr) [2]	-0.54 (0.428)	-0.93 (0.428)	-0.50 (0.140)	-0.56 (0.106)	
95% CI [2]	-1.51, 0.43	-1.89, 0.04	-0.77, -0.22	-0.77, -0.36	
Difference (95% CI) in CFB [2]		-0.38 (-1.62, 0.85)		-0.07 (-0.38, 0.24)	
p-value [3]		0.500		0.672	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Count	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	9	62	124	
Mean (StdDev)	0.56 (0.663)	0.78 (0.950)	1.08 (1.261)	0.83 (1.115)	
Median	0.38	0.21	0.50	0.29	
Min, Max	0.0, 1.5	0.0, 2.4	0.0, 5.9	0.0, 4.8	
C7D1 CFB					
n	4	9	62	122	
LS Mean (StdErr) [2]	-0.20 (0.488)	-0.95 (0.488)	-0.49 (0.152)	-0.57 (0.116)	
95% CI [2]	-1.30, 0.91	-2.05, 0.16	-0.79, -0.19	-0.79, -0.34	
Difference (95% CI) in CFB [2]		-0.75 (-2.16, 0.66)		-0.08 (-0.42, 0.26)	
Hedges'G (95% CI) in CFB		-0.52 (-1.98, 0.71)		-0.06 (-0.37, 0.24)	
p-value [3]		0.259		0.641	
					0.315

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	67	129	
Mean (StdDev)	2.18 (2.841)	3.76 (2.808)	3.12 (2.607)	2.83 (2.360)	
Median	1.18	3.36	2.43	2.36	
Min, Max	0.0, 6.4	0.0, 9.5	0.0, 9.5	0.0, 9.4	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	67	127	
Mean (StdDev)	1.68 (2.283)	3.35 (2.550)	2.42 (2.404)	2.22 (2.308)	
Median	0.79	2.57	1.85	1.36	
Min, Max	0.1, 5.0	0.0, 6.4	0.0, 9.1	0.0, 8.9	
C2D1 CFB					
n	4	10	67	125	
LS Mean (StdErr) [2]	-0.12 (1.179)	0.52 (1.179)	-0.63 (0.177)	-0.59 (0.139)	
95% CI [2]	-2.75, 2.50	-2.11, 3.14	-0.97, -0.28	-0.86, -0.31	
Difference (95% CI) in CFB [2]		0.64 (-2.70, 3.98)		0.04 (-0.36, 0.43)	
p-value [3]		0.677		0.849	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	8	67	127	
Mean (StdDev)	0.89 (0.714)	2.11 (2.277)	2.32 (2.317)	2.09 (2.245)	
Median	1.02	1.32	1.50	1.14	
Min, Max	0.0, 1.5	0.0, 5.1	0.0, 8.7	0.0, 9.5	
C3D1 CFB					
n	4	8	67	125	
LS Mean (StdErr) [2]	-1.36 (1.318)	-1.16 (1.318)	-0.70 (0.220)	-0.70 (0.173)	
95% CI [2]	-4.39, 1.68	-4.20, 1.87	-1.14, -0.27	-1.04, -0.36	
Difference (95% CI) in CFB [2]		0.19 (-3.70, 4.08)		0.00 (-0.49, 0.49)	
p-value [3]		0.913		0.993	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	4	9	64	126	
Mean (StdDev)	1.32 (2.055)	2.21 (2.206)	2.48 (2.362)	2.01 (2.277)	
Median	0.45	2.15	1.84	1.07	
Min, Max	0.0, 4.4	0.0, 6.2	0.0, 8.3	0.0, 8.9	
C4D1 CFB					
n	4	9	64	124	
LS Mean (StdErr) [2]	-0.95 (1.061)	-1.43 (1.061)	-0.63 (0.223)	-0.79 (0.172)	
95% CI [2]	-3.35, 1.45	-3.83, 0.97	-1.08, -0.19	-1.13, -0.45	
Difference (95% CI) in CFB [2]		-0.49 (-3.55, 2.57)		-0.15 (-0.64, 0.34)	
p-value [3]		0.728		0.543	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	9	63	128	
Mean (StdDev)	0.92 (0.979)	1.84 (1.513)	2.48 (2.389)	1.96 (2.247)	
Median	0.73	1.31	1.36	1.11	
Min, Max	0.0, 2.2	0.0, 4.1	0.0, 8.5	0.0, 9.0	
C5D1 CFB					
n	4	9	63	126	
LS Mean (StdErr) [2]	-1.20 (1.047)	-1.19 (1.047)	-0.67 (0.252)	-0.88 (0.190)	
95% CI [2]	-3.57, 1.17	-3.55, 1.18	-1.17, -0.17	-1.25, -0.50	
Difference (95% CI) in CFB [2]		0.01 (-3.01, 3.03)		-0.21 (-0.76, 0.35)	
p-value [3]		0.992		0.463	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Severity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	62	127	
Mean (StdDev)	1.02 (1.491)	1.89 (2.065)	2.26 (2.369)	1.81 (2.180)	
Median	0.43	1.21	1.36	1.07	
Min, Max	0.0, 3.2	0.0, 5.5	0.0, 8.6	0.0, 8.9	
C6D1 CFB					
n	4	9	62	125	
LS Mean (StdErr) [2]	-1.13 (0.801)	-1.19 (0.801)	-0.70 (0.240)	-0.92 (0.181)	
95% CI [2]	-2.94, 0.68	-3.00, 0.62	-1.17, -0.22	-1.27, -0.56	
Difference (95% CI) in CFB [2]		-0.07 (-2.38, 2.25)		-0.22 (-0.75, 0.31)	
p-value [3]		0.950		0.415	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.3.1.8a
Change from Baseline in Individual Symptom Scores of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

Diarrhea Severity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	9	62	124	
Mean (StdDev)	0.95 (0.869)	1.77 (2.085)	2.27 (2.478)	1.77 (2.201)	
Median	0.98	0.50	1.29	0.71	
Min, Max	0.0, 1.9	0.0, 5.1	0.0, 8.6	0.0, 8.7	
C7D1 CFB					
n	4	9	62	122	
LS Mean (StdErr) [2]	-1.03 (1.083)	-1.19 (1.083)	-0.71 (0.257)	-0.93 (0.196)	
95% CI [2]	-3.48, 1.42	-3.64, 1.26	-1.22, -0.20	-1.32, -0.54	
Difference (95% CI) in CFB [2]		-0.16 (-3.29, 2.96)		-0.22 (-0.79, 0.35)	
Hedges'G (95% CI) in CFB		-0.05 (-1.38, 1.26)		-0.10 (-0.41, 0.20)	
p-value [3]		0.909		0.453	
					0.742

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. CXD1 score is defined as the 14-day average of domain score prior to CXD1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating CXD1 score, then the CXD1 score is considered as missing.

[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-ind-sum-g-itt-thpy-a.sas Date: 15:00/07AUG2023

Table 35.2.2.4.2.1.1a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	130	11	9	
Mean (StdDev)	7.85 (1.664)	7.65 (1.708)	8.24 (1.806)	7.79 (1.545)	
Median	7.91	7.65	9.00	8.36	
Min, Max	4.1, 10.0	3.6, 10.0	5.1, 10.0	5.0, 9.6	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-age-a.sas Date: 15:11/07AUG2023

Table 35.2.2.4.2.1.1a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	60	126	11	9	
Mean (StdDev)	6.91 (2.007)	6.72 (2.002)	7.60 (2.725)	6.16 (2.314)	
Median	7.18	6.77	8.83	5.86	
Min, Max	2.4, 10.0	1.2, 10.0	1.6, 10.0	1.9, 9.0	
C2D1 CFB					
n	60	126	11	9	
LS Mean (StdErr) [2]	-0.95 (0.174)	-0.98 (0.129)	-2.65 (0.813)	-4.40 (1.031)	
95% CI [2]	-1.29, -0.60	-1.23, -0.72	-4.37, -0.92	-6.59, -2.22	
Difference (95% CI) in CFB [2]		-0.03 (-0.41, 0.36)		-1.76 (-3.36, -0.15)	
p-value [3]		0.884		0.034	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-age-a.sas Date: 15:11/07AUG2023

Table 35.2.2.4.2.1.1a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	60	124	11	9	
Mean (StdDev)	6.81 (2.375)	6.09 (2.230)	6.99 (3.086)	5.43 (2.813)	
Median	7.04	6.15	8.00	5.00	
Min, Max	0.9, 10.0	0.6, 10.0	0.9, 10.0	1.0, 8.5	
C3D1 CFB					
n	60	124	11	9	
LS Mean (StdErr) [2]	-1.01 (0.228)	-1.55 (0.170)	-3.35 (1.136)	-5.36 (1.441)	
95% CI [2]	-1.46, -0.56	-1.89, -1.22	-5.76, -0.94	-8.41, -2.30	
Difference (95% CI) in CFB [2]		-0.54 (-1.05, -0.04)		-2.01 (-4.25, 0.24)	
p-value [3]		0.036		0.076	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-age-a.sas Date: 15:11/07AUG2023

Table 35.2.2.4.2.1.1a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	58	124	10	9	
Mean (StdDev)	6.70 (2.444)	5.81 (2.442)	7.05 (2.852)	4.10 (3.118)	
Median	6.89	6.11	7.69	3.92	
Min, Max	1.5, 10.0	0.5, 10.0	2.0, 10.0	0.0, 8.2	
C4D1 CFB					
n	58	124	10	9	
LS Mean (StdErr) [2]	-1.20 (0.262)	-1.88 (0.191)	-2.57 (1.458)	-5.72 (1.836)	
95% CI [2]	-1.71, -0.68	-2.26, -1.50	-5.68, 0.54	-9.63, -1.80	
Difference (95% CI) in CFB [2]		-0.68 (-1.26, -0.11)		-3.15 (-6.06, -0.24)	
p-value [3]		0.020		0.036	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-age-a.sas Date: 15:11/07AUG2023

Table 35.2.2.4.2.1.1a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	58	126	9	9	
Mean (StdDev)	6.50 (2.561)	5.71 (2.358)	7.24 (3.031)	3.87 (3.186)	
Median	6.71	5.68	8.00	2.85	
Min, Max	0.9, 10.0	0.0, 10.0	1.1, 10.0	0.0, 8.6	
C5D1 CFB					
n	58	126	9	9	
LS Mean (StdErr) [2]	-1.30 (0.268)	-1.86 (0.193)	-2.90 (1.490)	-6.42 (1.858)	
95% CI [2]	-1.83, -0.77	-2.25, -1.48	-6.10, 0.29	-10.41, -2.44	
Difference (95% CI) in CFB [2]		-0.56 (-1.15, 0.03)		-3.52 (-6.53, -0.51)	
p-value [3]		0.061		0.025	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-age-a.sas Date: 15:11/07AUG2023

Table 35.2.2.4.2.1.1a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	56	125	10	9	
Mean (StdDev)	6.53 (2.606)	5.57 (2.504)	6.74 (3.294)	3.96 (3.229)	
Median	6.96	5.54	7.42	2.86	
Min, Max	0.8, 10.0	0.1, 10.0	0.4, 10.0	0.0, 8.7	
C6D1 CFB					
n	56	125	10	9	
LS Mean (StdErr) [2]	-1.28 (0.291)	-2.04 (0.208)	-3.55 (1.442)	-6.82 (1.815)	
95% CI [2]	-1.85, -0.70	-2.45, -1.63	-6.62, -0.47	-10.69, -2.95	
Difference (95% CI) in CFB [2]		-0.76 (-1.40, -0.12)		-3.27 (-6.15, -0.39)	
p-value [3]		0.020		0.029	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-age-a.sas Date: 15:11/07AUG2023

Table 35.2.2.4.2.1.1a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	56	122	10	9	
Mean (StdDev)	6.48 (2.623)	5.51 (2.514)	6.71 (3.347)	4.39 (3.075)	
Median	6.50	5.43	7.58	5.00	
Min, Max	1.2, 10.0	0.0, 10.0	0.2, 10.0	0.0, 8.9	
C7D1 CFB					
n	56	122	10	9	
LS Mean (StdErr) [2]	-1.37 (0.306)	-2.09 (0.220)	-3.45 (1.386)	-5.93 (1.745)	
95% CI [2]	-1.97, -0.77	-2.53, -1.66	-6.41, -0.50	-9.65, -2.21	
Difference (95% CI) in CFB [2]		-0.72 (-1.40, -0.05)		-2.47 (-5.24, 0.29)	
Hedges'G (95% CI) in CFB		-0.30 (-0.62, 0.02)		-0.49 (-1.55, 0.43)	
p-value [3]		0.036		0.076	
					0.243

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-age-a.sas Date: 15:11/07AUG2023

Table 35.2.2.4.2.1.2a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	17	41	54	98	
Mean (StdDev)	7.74 (1.860)	6.99 (1.548)	7.96 (1.633)	7.94 (1.679)	
Median	8.00	7.17	7.91	8.09	
Min, Max	4.6, 10.0	4.4, 10.0	4.1, 10.0	3.6, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-sex-a.sas Date: 15:12/07AUG2023

Table 35.2.2.4.2.1.2a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	17	40	54	95	
Mean (StdDev)	6.62 (2.341)	6.10 (1.804)	7.14 (2.062)	6.93 (2.064)	
Median	6.62	6.15	7.37	7.00	
Min, Max	2.5, 10.0	1.9, 9.2	1.6, 10.0	1.2, 10.0	
C2D1 CFB					
n	17	40	54	95	
LS Mean (StdErr) [2]	-1.16 (0.352)	-0.95 (0.242)	-0.87 (0.198)	-1.09 (0.166)	
95% CI [2]	-1.86, -0.45	-1.44, -0.46	-1.27, -0.48	-1.42, -0.76	
Difference (95% CI) in CFB [2]		0.21 (-0.59, 1.01)		-0.21 (-0.65, 0.22)	
p-value [3]		0.609		0.332	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-sex-a.sas Date: 15:12/07AUG2023

Table 35.2.2.4.2.1.2a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	40	54	93	
Mean (StdDev)	6.36 (2.889)	5.49 (2.005)	6.99 (2.338)	6.29 (2.340)	
Median	6.38	6.00	7.23	6.43	
Min, Max	0.9, 10.0	1.0, 9.0	0.9, 10.0	0.6, 10.0	
C3D1 CFB					
n	17	40	54	93	
LS Mean (StdErr) [2]	-1.33 (0.437)	-1.48 (0.300)	-1.00 (0.265)	-1.70 (0.222)	
95% CI [2]	-2.21, -0.46	-2.09, -0.88	-1.52, -0.47	-2.13, -1.26	
Difference (95% CI) in CFB [2]		-0.15 (-1.14, 0.84)		-0.70 (-1.28, -0.12)	
p-value [3]		0.762		0.019	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-sex-a.sas Date: 15:12/07AUG2023

Table 35.2.2.4.2.1.2a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	17	40	51	93	
Mean (StdDev)	6.08 (3.005)	5.31 (2.194)	6.97 (2.281)	5.86 (2.638)	
Median	5.04	5.48	7.07	6.21	
Min, Max	1.5, 10.0	0.8, 9.1	2.0, 10.0	0.0, 10.0	
C4D1 CFB					
n	17	40	51	93	
LS Mean (StdErr) [2]	-1.58 (0.483)	-1.61 (0.332)	-1.03 (0.313)	-2.16 (0.255)	
95% CI [2]	-2.55, -0.61	-2.28, -0.95	-1.65, -0.41	-2.66, -1.65	
Difference (95% CI) in CFB [2]		-0.04 (-1.13, 1.06)		-1.13 (-1.81, -0.45)	
p-value [3]		0.947		0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-sex-a.sas Date: 15:12/07AUG2023

Table 35.2.2.4.2.1.2a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	40	50	95	
Mean (StdDev)	6.17 (3.064)	5.09 (2.139)	6.74 (2.463)	5.80 (2.552)	
Median	6.21	5.26	6.89	5.79	
Min, Max	0.9, 10.0	1.1, 9.0	1.1, 10.0	0.0, 10.0	
C5D1 CFB					
n	17	40	50	95	
LS Mean (StdErr) [2]	-1.32 (0.491)	-1.68 (0.337)	-1.23 (0.326)	-2.13 (0.258)	
95% CI [2]	-2.31, -0.34	-2.36, -1.01	-1.87, -0.59	-2.64, -1.62	
Difference (95% CI) in CFB [2]		-0.36 (-1.48, 0.75)		-0.90 (-1.60, -0.19)	
p-value [3]		0.518		0.013	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-sex-a.sas Date: 15:12/07AUG2023

Table 35.2.2.4.2.1.2a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	17	40	49	94	
Mean (StdDev)	6.13 (3.061)	4.92 (2.080)	6.71 (2.572)	5.69 (2.738)	
Median	5.88	5.09	7.00	5.72	
Min, Max	0.8, 10.0	0.2, 9.4	0.4, 10.0	0.0, 10.0	
C6D1 CFB					
n	17	40	49	94	
LS Mean (StdErr) [2]	-1.42 (0.488)	-1.90 (0.336)	-1.26 (0.352)	-2.28 (0.279)	
95% CI [2]	-2.40, -0.44	-2.57, -1.22	-1.95, -0.56	-2.83, -1.72	
Difference (95% CI) in CFB [2]		-0.48 (-1.58, 0.63)		-1.02 (-1.79, -0.25)	
p-value [3]		0.394		0.010	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-sex-a.sas Date: 15:12/07AUG2023

Table 35.2.2.4.2.1.2a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	17	40	49	91	
Mean (StdDev)	5.87 (3.010)	5.13 (1.927)	6.74 (2.603)	5.56 (2.791)	
Median	5.57	5.15	7.21	5.54	
Min, Max	1.4, 10.0	1.1, 9.0	0.2, 10.0	0.0, 10.0	
C7D1 CFB					
n	17	40	49	91	
LS Mean (StdErr) [2]	-1.79 (0.490)	-1.81 (0.337)	-1.25 (0.366)	-2.37 (0.292)	
95% CI [2]	-2.77, -0.80	-2.49, -1.13	-1.98, -0.53	-2.95, -1.80	
Difference (95% CI) in CFB [2]		-0.02 (-1.14, 1.09)		-1.12 (-1.92, -0.32)	
Hedges'G (95% CI) in CFB		-0.01 (-0.59, 0.57)		-0.41 (-0.77, -0.06)	
p-value [3]		0.964		0.006	
					0.140

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-sex-a.sas Date: 15:12/07AUG2023

Table 35.2.2.4.2.1.3a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	33	58	38	81	
Mean (StdDev)	8.02 (1.636)	7.54 (1.787)	7.81 (1.732)	7.74 (1.627)	
Median	8.00	7.70	7.86	7.67	
Min, Max	4.1, 10.0	4.4, 10.0	4.6, 10.0	3.6, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-reg-a.sas Date: 15:13/07AUG2023

Table 35.2.2.4.2.1.3a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	33	57	38	78	
Mean (StdDev)	7.05 (2.184)	6.78 (1.912)	6.98 (2.103)	6.61 (2.104)	
Median	6.77	6.79	7.30	6.70	
Min, Max	2.4, 10.0	2.1, 9.9	1.6, 10.0	1.2, 10.0	
C2D1 CFB					
n	33	57	38	78	
LS Mean (StdErr) [2]	-1.12 (0.205)	-0.96 (0.172)	-0.80 (0.259)	-1.13 (0.194)	
95% CI [2]	-1.52, -0.71	-1.30, -0.61	-1.31, -0.29	-1.51, -0.74	
Difference (95% CI) in CFB [2]		0.16 (-0.30, 0.63)		-0.33 (-0.90, 0.24)	
p-value [3]		0.493		0.259	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-reg-a.sas Date: 15:13/07AUG2023

Table 35.2.2.4.2.1.3a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	33	56	38	77	
Mean (StdDev)	7.14 (2.503)	6.20 (2.169)	6.58 (2.451)	5.94 (2.344)	
Median	7.57	6.46	6.96	6.00	
Min, Max	0.9, 10.0	1.4, 10.0	0.9, 10.0	0.6, 10.0	
C3D1 CFB					
n	33	56	38	77	
LS Mean (StdErr) [2]	-0.99 (0.294)	-1.48 (0.247)	-1.16 (0.325)	-1.75 (0.244)	
95% CI [2]	-1.57, -0.40	-1.97, -0.99	-1.80, -0.51	-2.23, -1.27	
Difference (95% CI) in CFB [2]		-0.50 (-1.17, 0.17)		-0.59 (-1.31, 0.13)	
p-value [3]		0.144		0.106	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-reg-a.sas Date: 15:13/07AUG2023

Table 35.2.2.4.2.1.3a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	31	56	37	77	
Mean (StdDev)	7.02 (2.563)	5.83 (2.413)	6.52 (2.435)	5.60 (2.601)	
Median	8.00	6.11	6.86	5.91	
Min, Max	1.5, 10.0	0.5, 10.0	1.8, 10.0	0.0, 10.0	
C4D1 CFB					
n	31	56	37	77	
LS Mean (StdErr) [2]	-1.28 (0.358)	-1.96 (0.290)	-1.10 (0.368)	-2.04 (0.273)	
95% CI [2]	-1.99, -0.57	-2.54, -1.39	-1.83, -0.37	-2.59, -1.50	
Difference (95% CI) in CFB [2]		-0.68 (-1.48, 0.12)		-0.94 (-1.75, -0.13)	
p-value [3]		0.093		0.023	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-reg-a.sas Date: 15:13/07AUG2023

Table 35.2.2.4.2.1.3a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	30	57	37	78	
Mean (StdDev)	6.94 (2.785)	5.74 (2.182)	6.31 (2.473)	5.48 (2.639)	
Median	7.88	5.67	6.57	5.50	
Min, Max	0.9, 10.0	1.5, 10.0	1.1, 10.0	0.0, 10.0	
C5D1 CFB					
n	30	57	37	78	
LS Mean (StdErr) [2]	-1.29 (0.359)	-1.90 (0.280)	-1.21 (0.386)	-2.06 (0.286)	
95% CI [2]	-2.01, -0.58	-2.46, -1.34	-1.98, -0.45	-2.63, -1.50	
Difference (95% CI) in CFB [2]		-0.61 (-1.41, 0.19)		-0.85 (-1.70, -0.00)	
p-value [3]		0.136		0.049	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-reg-a.sas Date: 15:13/07AUG2023

Table 35.2.2.4.2.1.3a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	29	56	37	78	
Mean (StdDev)	7.02 (2.684)	5.73 (2.297)	6.20 (2.683)	5.27 (2.758)	
Median	8.00	5.57	6.64	5.42	
Min, Max	1.6, 10.0	0.4, 10.0	0.4, 10.0	0.0, 10.0	
C6D1 CFB					
n	29	56	37	78	
LS Mean (StdErr) [2]	-1.18 (0.392)	-1.94 (0.305)	-1.39 (0.399)	-2.33 (0.294)	
95% CI [2]	-1.96, -0.40	-2.55, -1.33	-2.18, -0.60	-2.91, -1.75	
Difference (95% CI) in CFB [2]		-0.76 (-1.64, 0.13)		-0.94 (-1.82, -0.06)	
p-value [3]		0.092		0.036	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-reg-a.sas Date: 15:13/07AUG2023

Table 35.2.2.4.2.1.3a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	30	55	36	76	
Mean (StdDev)	6.84 (2.873)	5.53 (2.268)	6.25 (2.590)	5.36 (2.762)	
Median	7.77	5.46	6.52	5.37	
Min, Max	1.2, 10.0	1.5, 10.0	0.2, 10.0	0.0, 10.0	
C7D1 CFB					
n	30	55	36	76	
LS Mean (StdErr) [2]	-1.44 (0.401)	-2.21 (0.322)	-1.36 (0.416)	-2.21 (0.305)	
95% CI [2]	-2.24, -0.65	-2.85, -1.57	-2.19, -0.54	-2.81, -1.60	
Difference (95% CI) in CFB [2]		-0.76 (-1.66, 0.14)		-0.84 (-1.76, 0.07)	
Hedges'G (95% CI) in CFB		-0.33 (-0.79, 0.12)		-0.32 (-0.73, 0.08)	
p-value [3]		0.096		0.071	
					0.873

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-reg-a.sas Date: 15:13/07AUG2023

Table 35.2.2.4.2.1.4a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-cou-a.sas Date: 15:14/07AUG2023

Table 35.2.2.4.2.1.4a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-cou-a.sas Date: 15:14/07AUG2023

Table 35.2.2.4.2.1.4a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-cou-a.sas Date: 15:14/07AUG2023

Table 35.2.2.4.2.1.4a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-cou-a.sas Date: 15:14/07AUG2023

Table 35.2.2.4.2.1.4a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-cou-a.sas Date: 15:14/07AUG2023

Table 35.2.2.4.2.1.5a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	26	52	45	87	
Mean (StdDev)	6.84 (1.731)	6.24 (1.287)	8.53 (1.309)	8.50 (1.292)	
Median	6.59	6.26	8.93	8.50	
Min, Max	4.1, 10.0	3.6, 8.8	5.5, 10.0	5.7, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-ism-a.sas Date: 15:15/07AUG2023

Table 35.2.2.4.2.1.5a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	26	50	45	85	
Mean (StdDev)	6.17 (2.012)	5.32 (1.564)	7.50 (2.056)	7.49 (1.820)	
Median	6.50	5.45	7.93	7.50	
Min, Max	2.4, 10.0	1.9, 8.1	1.6, 10.0	1.2, 10.0	
C2D1 CFB					
n	26	50	45	85	
LS Mean (StdErr) [2]	-0.73 (0.274)	-0.99 (0.203)	-1.10 (0.215)	-1.12 (0.172)	
95% CI [2]	-1.28, -0.19	-1.40, -0.59	-1.52, -0.67	-1.46, -0.78	
Difference (95% CI) in CFB [2]		-0.26 (-0.86, 0.34)		-0.02 (-0.52, 0.47)	
p-value [3]		0.392		0.920	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-ism-a.sas Date: 15:15/07AUG2023

Table 35.2.2.4.2.1.5a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	26	50	45	83	
Mean (StdDev)	5.80 (2.369)	4.63 (1.759)	7.45 (2.351)	6.90 (2.112)	
Median	6.07	4.70	8.00	7.33	
Min, Max	1.6, 10.0	1.0, 8.4	0.9, 10.0	0.6, 10.0	
C3D1 CFB					
n	26	50	45	83	
LS Mean (StdErr) [2]	-1.09 (0.341)	-1.67 (0.253)	-1.08 (0.287)	-1.62 (0.232)	
95% CI [2]	-1.77, -0.41	-2.17, -1.16	-1.65, -0.51	-2.08, -1.16	
Difference (95% CI) in CFB [2]		-0.58 (-1.32, 0.17)		-0.54 (-1.21, 0.12)	
p-value [3]		0.130		0.106	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-ism-a.sas Date: 15:15/07AUG2023

Table 35.2.2.4.2.1.5a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	24	49	44	84	
Mean (StdDev)	5.50 (2.369)	4.28 (1.880)	7.43 (2.302)	6.52 (2.484)	
Median	5.60	4.38	8.11	6.55	
Min, Max	1.8, 10.0	0.8, 7.1	1.5, 10.0	0.0, 10.0	
C4D1 CFB					
n	24	49	44	84	
LS Mean (StdErr) [2]	-1.21 (0.370)	-1.95 (0.268)	-1.14 (0.344)	-2.03 (0.272)	
95% CI [2]	-1.95, -0.47	-2.48, -1.41	-1.82, -0.46	-2.57, -1.49	
Difference (95% CI) in CFB [2]		-0.74 (-1.55, 0.08)		-0.89 (-1.67, -0.11)	
p-value [3]		0.076		0.026	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-ism-a.sas Date: 15:15/07AUG2023

Table 35.2.2.4.2.1.5a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	51	44	84	
Mean (StdDev)	5.19 (2.392)	4.33 (1.808)	7.33 (2.441)	6.36 (2.481)	
Median	4.46	4.57	8.00	6.56	
Min, Max	1.3, 10.0	1.1, 8.0	0.9, 10.0	0.0, 10.0	
C5D1 CFB					
n	23	51	44	84	
LS Mean (StdErr) [2]	-1.35 (0.353)	-1.77 (0.246)	-1.21 (0.362)	-2.16 (0.287)	
95% CI [2]	-2.06, -0.65	-2.26, -1.28	-1.93, -0.49	-2.73, -1.59	
Difference (95% CI) in CFB [2]		-0.42 (-1.19, 0.36)		-0.95 (-1.77, -0.13)	
p-value [3]		0.288		0.024	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-ism-a.sas Date: 15:15/07AUG2023

Table 35.2.2.4.2.1.5a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	24	52	42	82	
Mean (StdDev)	5.32 (2.446)	4.23 (1.809)	7.27 (2.595)	6.24 (2.692)	
Median	5.17	4.43	8.00	6.71	
Min, Max	0.8, 10.0	0.2, 8.3	0.4, 10.0	0.0, 10.0	
C6D1 CFB					
n	24	52	42	82	
LS Mean (StdErr) [2]	-1.27 (0.378)	-1.94 (0.266)	-1.34 (0.389)	-2.35 (0.305)	
95% CI [2]	-2.03, -0.52	-2.47, -1.41	-2.11, -0.57	-2.96, -1.75	
Difference (95% CI) in CFB [2]		-0.66 (-1.49, 0.17)		-1.01 (-1.90, -0.13)	
p-value [3]		0.115		0.026	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-ism-a.sas Date: 15:15/07AUG2023

Table 35.2.2.4.2.1.5a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	23	51	43	80	
Mean (StdDev)	5.32 (2.384)	4.32 (1.916)	7.16 (2.691)	6.14 (2.673)	
Median	5.29	4.71	8.00	6.05	
Min, Max	1.6, 10.0	1.1, 8.4	0.2, 10.0	0.0, 10.0	
C7D1 CFB					
n	23	51	43	80	
LS Mean (StdErr) [2]	-1.48 (0.389)	-1.95 (0.271)	-1.40 (0.397)	-2.40 (0.320)	
95% CI [2]	-2.26, -0.71	-2.49, -1.41	-2.19, -0.62	-3.04, -1.77	
Difference (95% CI) in CFB [2]		-0.47 (-1.33, 0.38)		-1.00 (-1.91, -0.09)	
Hedges'G (95% CI) in CFB		-0.24 (-0.75, 0.25)		-0.36 (-0.74, 0.01)	
p-value [3]		0.274		0.031	
					0.444

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-ism-a.sas Date: 15:15/07AUG2023

Table 35.2.2.4.2.1.6a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	15	28	56	111	
Mean (StdDev)	7.35 (1.994)	7.73 (1.725)	8.06 (1.571)	7.64 (1.692)	
Median	7.43	7.61	8.00	7.69	
Min, Max	4.1, 10.0	4.6, 10.0	4.6, 10.0	3.6, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-tryp-a.sas Date: 15:15/07AUG2023

Table 35.2.2.4.2.1.6a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	56	108	
Mean (StdDev)	6.00 (2.396)	6.73 (1.951)	7.29 (1.983)	6.67 (2.045)	
Median	6.07	6.68	7.71	6.80	
Min, Max	1.6, 9.9	2.1, 10.0	2.5, 10.0	1.2, 10.0	
C2D1 CFB					
n	15	27	56	108	
LS Mean (StdErr) [2]	-1.30 (0.413)	-1.06 (0.299)	-0.75 (0.168)	-0.96 (0.124)	
95% CI [2]	-2.14, -0.47	-1.66, -0.45	-1.08, -0.42	-1.20, -0.71	
Difference (95% CI) in CFB [2]		0.25 (-0.76, 1.26)		-0.20 (-0.61, 0.20)	
p-value [3]		0.622		0.325	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-tryp-a.sas Date: 15:15/07AUG2023

Table 35.2.2.4.2.1.6a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	27	56	106	
Mean (StdDev)	5.82 (2.878)	6.37 (2.117)	7.12 (2.306)	5.96 (2.306)	
Median	5.00	6.21	7.57	6.04	
Min, Max	0.9, 10.0	1.4, 10.0	0.9, 10.0	0.6, 10.0	
C3D1 CFB					
n	15	27	56	106	
LS Mean (StdErr) [2]	-1.58 (0.499)	-1.45 (0.361)	-0.94 (0.225)	-1.67 (0.166)	
95% CI [2]	-2.59, -0.57	-2.18, -0.72	-1.38, -0.49	-2.00, -1.34	
Difference (95% CI) in CFB [2]		0.13 (-1.09, 1.35)		-0.73 (-1.28, -0.19)	
p-value [3]		0.828		0.009	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-tryp-a.sas Date: 15:15/07AUG2023

Table 35.2.2.4.2.1.6a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	14	27	54	106	
Mean (StdDev)	5.60 (2.846)	6.07 (2.225)	7.05 (2.323)	5.60 (2.587)	
Median	4.95	5.91	7.30	6.08	
Min, Max	2.0, 9.7	0.8, 10.0	1.5, 10.0	0.0, 10.0	
C4D1 CFB					
n	14	27	54	106	
LS Mean (StdErr) [2]	-1.75 (0.544)	-1.74 (0.383)	-1.00 (0.268)	-2.05 (0.194)	
95% CI [2]	-2.85, -0.65	-2.51, -0.96	-1.53, -0.47	-2.43, -1.67	
Difference (95% CI) in CFB [2]		0.01 (-1.31, 1.33)		-1.05 (-1.69, -0.41)	
p-value [3]		0.985		0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-tryp-a.sas Date: 15:15/07AUG2023

Table 35.2.2.4.2.1.6a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	28	53	107	
Mean (StdDev)	5.70 (2.774)	6.10 (2.138)	6.83 (2.548)	5.46 (2.519)	
Median	5.07	5.88	7.21	5.43	
Min, Max	1.1, 10.0	1.5, 10.0	0.9, 10.0	0.0, 10.0	
C5D1 CFB					
n	14	28	53	107	
LS Mean (StdErr) [2]	-1.55 (0.541)	-1.60 (0.373)	-1.25 (0.281)	-2.20 (0.200)	
95% CI [2]	-2.64, -0.46	-2.36, -0.85	-1.81, -0.70	-2.59, -1.80	
Difference (95% CI) in CFB [2]		-0.05 (-1.36, 1.26)		-0.95 (-1.61, -0.28)	
p-value [3]		0.937		0.006	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-tryp-a.sas Date: 15:15/07AUG2023

Table 35.2.2.4.2.1.6a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	28	52	106	
Mean (StdDev)	5.29 (3.112)	5.92 (2.217)	6.90 (2.494)	5.34 (2.659)	
Median	4.32	5.42	7.18	5.52	
Min, Max	0.4, 10.0	2.0, 10.0	0.8, 10.0	0.0, 10.0	
C6D1 CFB					
n	14	28	52	106	
LS Mean (StdErr) [2]	-1.97 (0.597)	-1.78 (0.412)	-1.11 (0.294)	-2.28 (0.209)	
95% CI [2]	-3.18, -0.77	-2.61, -0.95	-1.70, -0.53	-2.69, -1.87	
Difference (95% CI) in CFB [2]		0.19 (-1.25, 1.64)		-1.17 (-1.87, -0.46)	
p-value [3]		0.791		0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-tryp-a.sas Date: 15:15/07AUG2023

Table 35.2.2.4.2.1.6a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	14	27	52	104	
Mean (StdDev)	5.20 (3.289)	5.85 (2.305)	6.87 (2.458)	5.32 (2.619)	
Median	4.50	5.22	7.25	5.44	
Min, Max	0.2, 10.0	1.8, 10.0	1.4, 10.0	0.0, 10.0	
C7D1 CFB					
n	14	27	52	104	
LS Mean (StdErr) [2]	-2.13 (0.647)	-1.85 (0.453)	-1.18 (0.298)	-2.27 (0.213)	
95% CI [2]	-3.44, -0.82	-2.77, -0.94	-1.77, -0.59	-2.69, -1.85	
Difference (95% CI) in CFB [2]		0.28 (-1.30, 1.86)		-1.09 (-1.81, -0.38)	
Hedges'G (95% CI) in CFB		0.12 (-0.54, 0.79)		-0.50 (-0.85, -0.17)	
p-value [3]		0.722		0.003	
					0.098

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-tryp-a.sas Date: 15:15/07AUG2023

Table 35.2.2.4.2.1.7a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	67	129	4	10	
Mean (StdDev)	7.91 (1.657)	7.60 (1.686)	7.89 (2.323)	8.35 (1.706)	
Median	8.00	7.67	8.39	8.79	
Min, Max	4.1, 10.0	3.6, 10.0	4.8, 10.0	5.5, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-ecog-a.sas Date: 15:16/07AUG2023

Table 35.2.2.4.2.1.7a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	67	125	4	10	
Mean (StdDev)	7.03 (2.148)	6.65 (1.998)	6.67 (1.954)	7.16 (2.334)	
Median	7.29	6.71	7.31	7.35	
Min, Max	1.6, 10.0	1.2, 10.0	3.9, 8.1	3.2, 10.0	
C2D1 CFB					
n	67	125	4	10	
LS Mean (StdErr) [2]	-0.94 (0.174)	-1.06 (0.137)	-0.63 (1.042)	-0.56 (0.798)	
95% CI [2]	-1.28, -0.60	-1.33, -0.79	-2.95, 1.69	-2.34, 1.21	
Difference (95% CI) in CFB [2]		-0.12 (-0.51, 0.27)		0.06 (-1.86, 1.99)	
p-value [3]		0.556		0.942	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-ecog-a.sas Date: 15:16/07AUG2023

Table 35.2.2.4.2.1.7a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	67	123	4	10	
Mean (StdDev)	6.86 (2.488)	5.97 (2.221)	6.58 (2.556)	7.00 (2.723)	
Median	7.23	6.07	7.17	7.75	
Min, Max	0.9, 10.0	0.6, 10.0	3.1, 8.9	3.1, 10.0	
C3D1 CFB					
n	67	123	4	10	
LS Mean (StdErr) [2]	-1.07 (0.225)	-1.67 (0.178)	-0.94 (1.653)	-1.00 (1.266)	
95% CI [2]	-1.51, -0.62	-2.02, -1.32	-4.62, 2.74	-3.82, 1.82	
Difference (95% CI) in CFB [2]		-0.60 (-1.10, -0.09)		-0.06 (-3.12, 3.00)	
p-value [3]		0.021		0.965	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-ecog-a.sas Date: 15:16/07AUG2023

Table 35.2.2.4.2.1.7a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	64	123	4	10	
Mean (StdDev)	6.78 (2.495)	5.63 (2.466)	6.21 (2.672)	6.52 (3.110)	
Median	7.00	5.91	6.43	7.06	
Min, Max	1.5, 10.0	0.0, 10.0	3.1, 8.9	1.4, 10.0	
C4D1 CFB					
n	64	123	4	10	
LS Mean (StdErr) [2]	-1.14 (0.262)	-2.02 (0.202)	-1.13 (1.992)	-1.29 (1.525)	
95% CI [2]	-1.66, -0.63	-2.42, -1.62	-5.57, 3.31	-4.69, 2.11	
Difference (95% CI) in CFB [2]		-0.88 (-1.46, -0.30)		-0.16 (-3.84, 3.53)	
p-value [3]		0.003		0.926	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-ecog-a.sas Date: 15:16/07AUG2023

Table 35.2.2.4.2.1.7a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	63	125	4	10	
Mean (StdDev)	6.66 (2.626)	5.50 (2.365)	5.59 (2.576)	6.70 (3.304)	
Median	6.93	5.49	5.69	8.00	
Min, Max	0.9, 10.0	0.0, 10.0	2.5, 8.5	1.1, 10.0	
C5D1 CFB					
n	63	125	4	10	
LS Mean (StdErr) [2]	-1.19 (0.269)	-2.04 (0.203)	-1.84 (2.112)	-1.30 (1.617)	
95% CI [2]	-1.72, -0.66	-2.44, -1.63	-6.55, 2.87	-4.91, 2.30	
Difference (95% CI) in CFB [2]		-0.85 (-1.45, -0.25)		0.54 (-3.37, 4.45)	
p-value [3]		0.006		0.766	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-ecog-a.sas Date: 15:16/07AUG2023

Table 35.2.2.4.2.1.7a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	62	124	4	10	
Mean (StdDev)	6.59 (2.735)	5.38 (2.504)	6.12 (2.192)	6.45 (3.342)	
Median	6.96	5.38	6.17	7.23	
Min, Max	0.4, 10.0	0.0, 10.0	3.6, 8.6	1.0, 10.0	
C6D1 CFB					
n	62	124	4	10	
LS Mean (StdErr) [2]	-1.26 (0.290)	-2.19 (0.219)	-1.37 (1.938)	-1.63 (1.484)	
95% CI [2]	-1.83, -0.69	-2.62, -1.76	-5.68, 2.95	-4.94, 1.67	
Difference (95% CI) in CFB [2]		-0.93 (-1.58, -0.28)		-0.27 (-3.85, 3.32)	
p-value [3]		0.005		0.871	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-ecog-a.sas Date: 15:16/07AUG2023

Table 35.2.2.4.2.1.7a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	63	121	3	10	
Mean (StdDev)	6.51 (2.757)	5.36 (2.482)	6.70 (2.038)	6.32 (3.379)	
Median	6.57	5.25	7.21	7.14	
Min, Max	0.2, 10.0	0.0, 10.0	4.5, 8.4	1.4, 10.0	
C7D1 CFB					
n	63	121	3	10	
LS Mean (StdErr) [2]	-1.35 (0.295)	-2.22 (0.226)	-1.55 (2.364)	-1.49 (1.654)	
95% CI [2]	-1.93, -0.77	-2.67, -1.77	-6.90, 3.80	-5.23, 2.25	
Difference (95% CI) in CFB [2]		-0.87 (-1.53, -0.21)		0.06 (-4.35, 4.47)	
Hedges'G (95% CI) in CFB		-0.36 (-0.67, -0.05)		0.01 (-1.44, 1.46)	
p-value [3]		0.010		0.976	
					0.464

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-ecog-a.sas Date: 15:16/07AUG2023

Table 35.2.2.4.2.1.8a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	67	129	
Mean (StdDev)	8.34 (0.493)	8.76 (1.494)	7.88 (1.723)	7.57 (1.682)	
Median	8.21	8.93	7.90	7.64	
Min, Max	7.9, 9.0	5.1, 10.0	4.1, 10.0	3.6, 10.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-thpy-a.sas Date: 15:17/07AUG2023

Table 35.2.2.4.2.1.8a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	67	125	
Mean (StdDev)	7.78 (0.998)	7.79 (1.454)	6.97 (2.170)	6.60 (2.037)	
Median	7.93	8.24	7.21	6.71	
Min, Max	6.4, 8.8	5.1, 10.0	1.6, 10.0	1.2, 10.0	
C2D1 CFB					
n	4	10	67	125	
LS Mean (StdErr) [2]	-0.75 (0.621)	-1.04 (0.621)	-0.95 (0.178)	-1.05 (0.140)	
95% CI [2]	-2.13, 0.64	-2.43, 0.34	-1.31, -0.60	-1.32, -0.77	
Difference (95% CI) in CFB [2]		-0.30 (-2.06, 1.47)		-0.09 (-0.49, 0.30)	
p-value [3]		0.717		0.638	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-thpy-a.sas Date: 15:17/07AUG2023

Table 35.2.2.4.2.1.8a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	8	67	125	
Mean (StdDev)	7.73 (0.584)	6.99 (1.990)	6.79 (2.535)	5.99 (2.277)	
Median	7.79	7.32	7.07	6.07	
Min, Max	7.0, 8.4	3.7, 10.0	0.9, 10.0	0.6, 10.0	
C3D1 CFB					
n	4	8	67	125	
LS Mean (StdErr) [2]	-0.50 (1.096)	-1.57 (1.096)	-1.12 (0.229)	-1.63 (0.180)	
95% CI [2]	-3.03, 2.03	-4.10, 0.95	-1.57, -0.66	-1.99, -1.28	
Difference (95% CI) in CFB [2]		-1.08 (-4.31, 2.16)		-0.52 (-1.03, -0.01)	
p-value [3]		0.464		0.048	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-thpy-a.sas Date: 15:17/07AUG2023

Table 35.2.2.4.2.1.8a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	4	9	64	124	
Mean (StdDev)	6.79 (1.363)	6.28 (2.050)	6.75 (2.548)	5.65 (2.549)	
Median	7.16	6.23	6.96	6.04	
Min, Max	4.9, 8.0	3.6, 10.0	1.5, 10.0	0.0, 10.0	
C4D1 CFB					
n	4	9	64	124	
LS Mean (StdErr) [2]	-1.81 (1.083)	-2.75 (1.083)	-1.12 (0.270)	-1.94 (0.207)	
95% CI [2]	-4.26, 0.64	-5.20, -0.30	-1.65, -0.59	-2.34, -1.53	
Difference (95% CI) in CFB [2]		-0.94 (-4.07, 2.18)		-0.81 (-1.41, -0.22)	
p-value [3]		0.512		0.008	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-thpy-a.sas Date: 15:17/07AUG2023

Table 35.2.2.4.2.1.8a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	9	63	126	
Mean (StdDev)	5.87 (2.269)	5.82 (2.206)	6.64 (2.646)	5.57 (2.475)	
Median	6.03	4.83	6.85	5.62	
Min, Max	3.4, 8.0	3.1, 10.0	0.9, 10.0	0.0, 10.0	
C5D1 CFB					
n	4	9	63	126	
LS Mean (StdErr) [2]	-3.00 (1.213)	-3.64 (1.213)	-1.13 (0.274)	-1.88 (0.206)	
95% CI [2]	-5.74, -0.25	-6.38, -0.89	-1.67, -0.59	-2.29, -1.47	
Difference (95% CI) in CFB [2]		-0.64 (-4.14, 2.86)		-0.75 (-1.35, -0.15)	
p-value [3]		0.689		0.015	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-thpy-a.sas Date: 15:17/07AUG2023

Table 35.2.2.4.2.1.8a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	62	125	
Mean (StdDev)	5.73 (2.009)	5.70 (2.323)	6.61 (2.736)	5.44 (2.601)	
Median	5.45	4.25	7.04	5.50	
Min, Max	4.0, 8.0	3.1, 10.0	0.4, 10.0	0.0, 10.0	
C6D1 CFB					
n	4	9	62	125	
LS Mean (StdErr) [2]	-3.17 (1.297)	-3.93 (1.297)	-1.17 (0.291)	-2.06 (0.219)	
95% CI [2]	-6.11, -0.24	-6.87, -1.00	-1.74, -0.59	-2.49, -1.62	
Difference (95% CI) in CFB [2]		-0.76 (-4.50, 2.98)		-0.89 (-1.53, -0.25)	
p-value [3]		0.657		0.007	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-thpy-a.sas Date: 15:17/07AUG2023

Table 35.2.2.4.2.1.8a
Change from Baseline of Lead (Most Severe) Symptoms of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	9	62	122	
Mean (StdDev)	5.75 (2.147)	5.71 (2.080)	6.57 (2.757)	5.41 (2.596)	
Median	5.68	5.21	6.89	5.43	
Min, Max	3.6, 8.0	3.2, 10.0	0.2, 10.0	0.0, 10.0	
C7D1 CFB					
n	4	9	62	122	
LS Mean (StdErr) [2]	-2.94 (1.299)	-3.57 (1.299)	-1.27 (0.301)	-2.10 (0.229)	
95% CI [2]	-5.88, -0.00	-6.51, -0.63	-1.87, -0.68	-2.55, -1.65	
Difference (95% CI) in CFB [2]		-0.63 (-4.38, 3.12)		-0.83 (-1.50, -0.16)	
Hedges'G (95% CI) in CFB		-0.16 (-1.52, 1.13)		-0.33 (-0.65, -0.03)	
p-value [3]		0.714		0.015	
					0.769

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: The "lead symptom" score refers to the individual symptom with highest score at Baseline in each patient. If patient has tie with multiple Lead (Most Severe) Symptom, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-sum-g-itt-thpy-a.sas Date: 15:17/07AUG2023

Table 35.2.2.4.4.1.1a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	130	11	9	
Mean (StdDev)	18.14 (6.287)	17.34 (6.074)	21.00 (6.756)	19.95 (5.095)	
Median	18.50	16.52	20.71	22.00	
Min, Max	4.8, 30.0	5.6, 30.0	11.3, 30.0	11.4, 26.9	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-age-a.sas Date: 15:26/07AUG2023

Table 35.2.2.4.4.1.1a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	60	126	11	9	
Mean (StdDev)	16.10 (6.467)	14.45 (6.104)	18.45 (9.080)	12.85 (7.012)	
Median	16.41	13.64	18.86	11.29	
Min, Max	3.7, 29.2	2.8, 30.0	5.6, 29.8	4.9, 25.9	
C2D1 CFB					
n	60	126	11	9	
LS Mean (StdErr) [2]	-1.99 (0.478)	-2.99 (0.355)	-5.22 (2.500)	-11.28 (3.171)	
95% CI [2]	-2.93, -1.04	-3.69, -2.29	-10.52, 0.08	-18.01, -4.56	
Difference (95% CI) in CFB [2]		-1.01 (-2.06, 0.05)		-6.06 (-11.01, -1.12)	
p-value [3]		0.062		0.019	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-age-a.sas Date: 15:26/07AUG2023

Table 35.2.2.4.4.1.1a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	60	124	11	9	
Mean (StdDev)	15.56 (7.225)	12.97 (6.212)	17.68 (8.828)	10.87 (7.948)	
Median	16.15	11.90	21.00	9.21	
Min, Max	1.4, 29.4	2.6, 30.0	6.0, 28.6	1.5, 24.1	
C3D1 CFB					
n	60	124	11	9	
LS Mean (StdErr) [2]	-2.26 (0.591)	-4.25 (0.440)	-5.63 (2.997)	-12.85 (3.801)	
95% CI [2]	-3.42, -1.09	-5.11, -3.38	-11.98, 0.72	-20.91, -4.79	
Difference (95% CI) in CFB [2]		-1.99 (-3.30, -0.68)		-7.22 (-13.15, -1.30)	
p-value [3]		0.003		0.020	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-age-a.sas Date: 15:26/07AUG2023

Table 35.2.2.4.4.1.1a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	58	124	10	9	
Mean (StdDev)	15.18 (7.156)	12.07 (6.519)	18.05 (8.938)	9.54 (8.764)	
Median	14.79	10.96	21.00	6.23	
Min, Max	1.0, 29.7	0.7, 29.9	6.9, 28.6	0.7, 24.0	
C4D1 CFB					
n	58	124	10	9	
LS Mean (StdErr) [2]	-2.74 (0.672)	-5.16 (0.492)	-5.43 (3.615)	-13.65 (4.552)	
95% CI [2]	-4.06, -1.41	-6.14, -4.19	-13.14, 2.27	-23.35, -3.95	
Difference (95% CI) in CFB [2]		-2.43 (-3.90, -0.95)		-8.22 (-15.44, -1.00)	
p-value [3]		0.001		0.028	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-age-a.sas Date: 15:26/07AUG2023

Table 35.2.2.4.4.1.1a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	58	126	9	9	
Mean (StdDev)	14.62 (7.495)	11.79 (6.405)	20.39 (7.851)	8.39 (8.819)	
Median	14.89	10.82	22.36	5.57	
Min, Max	1.5, 29.9	1.7, 30.0	6.4, 30.0	0.3, 23.2	
C5D1 CFB					
n	58	126	9	9	
LS Mean (StdErr) [2]	-3.35 (0.724)	-5.46 (0.523)	-4.66 (3.546)	-15.68 (4.423)	
95% CI [2]	-4.78, -1.92	-6.49, -4.43	-12.26, 2.95	-25.17, -6.20	
Difference (95% CI) in CFB [2]		-2.11 (-3.70, -0.52)		-11.03 (-18.20, -3.86)	
p-value [3]		0.010		0.005	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-age-a.sas Date: 15:26/07AUG2023

Table 35.2.2.4.4.1.1a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	56	125	10	9	
Mean (StdDev)	14.49 (7.365)	11.30 (6.508)	18.45 (9.462)	8.22 (8.393)	
Median	14.89	10.50	21.29	7.14	
Min, Max	0.5, 29.8	0.7, 30.0	1.6, 30.0	0.1, 22.9	
C6D1 CFB					
n	56	125	10	9	
LS Mean (StdErr) [2]	-3.23 (0.779)	-5.89 (0.557)	-5.38 (3.521)	-15.31 (4.433)	
95% CI [2]	-4.77, -1.69	-6.99, -4.79	-12.88, 2.13	-24.76, -5.86	
Difference (95% CI) in CFB [2]		-2.66 (-4.38, -0.94)		-9.93 (-16.97, -2.90)	
p-value [3]		0.003		0.009	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-age-a.sas Date: 15:26/07AUG2023

Table 35.2.2.4.4.1.1a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	56	122	10	9	
Mean (StdDev)	14.78 (7.232)	11.12 (6.400)	18.64 (8.911)	9.56 (8.667)	
Median	14.82	10.48	21.77	8.36	
Min, Max	0.5, 30.0	0.1, 30.0	5.9, 29.9	0.0, 22.6	
C7D1 CFB					
n	56	122	10	9	
LS Mean (StdErr) [2]	-2.94 (0.795)	-5.93 (0.573)	-5.25 (3.248)	-13.19 (4.090)	
95% CI [2]	-4.51, -1.37	-7.06, -4.80	-12.18, 1.67	-21.91, -4.48	
Difference (95% CI) in CFB [2]		-2.99 (-4.74, -1.23)		-7.94 (-14.43, -1.45)	
Hedges'G (95% CI) in CFB		-0.48 (-0.81, -0.16)		-0.67 (-1.77, 0.23)	
p-value [3]		<0.001		0.020	
					0.133

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-age-a.sas Date: 15:26/07AUG2023

Table 35.2.2.4.4.1.2a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	17	41	54	98	
Mean (StdDev)	18.11 (6.945)	16.12 (5.381)	18.73 (6.277)	18.09 (6.220)	
Median	19.71	15.18	18.64	18.11	
Min, Max	4.8, 30.0	7.7, 30.0	6.8, 30.0	5.6, 30.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-sex-a.sas Date: 15:27/07AUG2023

Table 35.2.2.4.4.1.2a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	17	40	54	95	
Mean (StdDev)	15.52 (6.727)	13.55 (5.759)	16.76 (7.004)	14.67 (6.311)	
Median	16.36	12.41	16.50	14.71	
Min, Max	3.7, 29.2	4.9, 26.8	4.6, 29.8	2.8, 30.0	
C2D1 CFB					
n	17	40	54	95	
LS Mean (StdErr) [2]	-2.89 (0.898)	-2.90 (0.618)	-1.84 (0.572)	-3.34 (0.479)	
95% CI [2]	-4.69, -1.09	-4.14, -1.66	-2.97, -0.70	-4.29, -2.40	
Difference (95% CI) in CFB [2]		-0.02 (-2.06, 2.02)		-1.51 (-2.77, -0.25)	
p-value [3]		0.987		0.019	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-sex-a.sas Date: 15:27/07AUG2023

Table 35.2.2.4.4.1.2a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	40	54	93	
Mean (StdDev)	14.95 (8.339)	12.15 (5.622)	16.18 (7.228)	13.12 (6.618)	
Median	16.29	10.55	15.47	12.29	
Min, Max	1.4, 28.9	2.7, 24.1	4.5, 29.4	1.5, 30.0	
C3D1 CFB					
n	17	40	54	93	
LS Mean (StdErr) [2]	-3.12 (1.050)	-3.99 (0.723)	-2.16 (0.708)	-4.68 (0.593)	
95% CI [2]	-5.23, -1.01	-5.44, -2.54	-3.56, -0.76	-5.85, -3.51	
Difference (95% CI) in CFB [2]		-0.87 (-3.26, 1.51)		-2.52 (-4.08, -0.96)	
p-value [3]		0.466		0.002	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-sex-a.sas Date: 15:27/07AUG2023

Table 35.2.2.4.4.1.2a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	17	40	51	93	
Mean (StdDev)	14.28 (7.942)	11.56 (6.148)	16.05 (7.293)	12.05 (6.928)	
Median	14.50	10.45	17.14	10.71	
Min, Max	1.0, 29.7	1.8, 24.5	3.8, 29.6	0.7, 29.9	
C4D1 CFB					
n	17	40	51	93	
LS Mean (StdErr) [2]	-3.64 (1.222)	-4.44 (0.841)	-2.50 (0.802)	-5.86 (0.654)	
95% CI [2]	-6.09, -1.19	-6.13, -2.76	-4.09, -0.91	-7.15, -4.56	
Difference (95% CI) in CFB [2]		-0.81 (-3.58, 1.97)		-3.36 (-5.10, -1.62)	
p-value [3]		0.563		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-sex-a.sas Date: 15:27/07AUG2023

Table 35.2.2.4.4.1.2a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	40	50	95	
Mean (StdDev)	14.61 (8.214)	11.09 (5.892)	15.66 (7.642)	11.76 (6.904)	
Median	15.92	10.85	15.41	10.71	
Min, Max	1.5, 29.9	1.9, 25.2	1.7, 30.0	0.3, 30.0	
C5D1 CFB					
n	17	40	50	95	
LS Mean (StdErr) [2]	-3.21 (1.214)	-4.82 (0.835)	-2.99 (0.882)	-6.17 (0.697)	
95% CI [2]	-5.65, -0.78	-6.50, -3.15	-4.74, -1.25	-7.55, -4.80	
Difference (95% CI) in CFB [2]		-1.61 (-4.37, 1.15)		-3.18 (-5.09, -1.27)	
p-value [3]		0.246		0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-sex-a.sas Date: 15:27/07AUG2023

Table 35.2.2.4.4.1.2a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	17	40	49	94	
Mean (StdDev)	14.95 (7.753)	10.68 (5.218)	15.13 (7.853)	11.26 (7.201)	
Median	15.67	10.42	14.36	10.36	
Min, Max	1.0, 29.6	2.6, 22.4	0.5, 30.0	0.1, 30.0	
C6D1 CFB					
n	17	40	49	94	
LS Mean (StdErr) [2]	-2.93 (1.202)	-5.29 (0.828)	-3.25 (0.947)	-6.57 (0.750)	
95% CI [2]	-5.34, -0.52	-6.95, -3.63	-5.12, -1.38	-8.05, -5.08	
Difference (95% CI) in CFB [2]		-2.36 (-5.09, 0.37)		-3.32 (-5.38, -1.25)	
p-value [3]		0.089		0.002	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-sex-a.sas Date: 15:27/07AUG2023

Table 35.2.2.4.4.1.2a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	17	40	49	91	
Mean (StdDev)	15.31 (7.720)	10.96 (5.273)	15.39 (7.588)	11.03 (7.066)	
Median	16.69	10.68	15.00	9.33	
Min, Max	2.9, 30.0	2.4, 22.5	0.5, 30.0	0.0, 30.0	
C7D1 CFB					
n	17	40	49	91	
LS Mean (StdErr) [2]	-2.67 (1.212)	-5.15 (0.834)	-3.01 (0.944)	-6.65 (0.754)	
95% CI [2]	-5.10, -0.24	-6.82, -3.47	-4.87, -1.14	-8.14, -5.15	
Difference (95% CI) in CFB [2]		-2.48 (-5.23, 0.27)		-3.64 (-5.70, -1.58)	
Hedges'G (95% CI) in CFB		-0.47 (-1.08, 0.10)		-0.52 (-0.88, -0.17)	
p-value [3]		0.077		<0.001	
					0.547

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-sex-a.sas Date: 15:27/07AUG2023

Table 35.2.2.4.4.1.3a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	33	58	38	81	
Mean (StdDev)	20.00 (5.955)	17.54 (6.243)	17.35 (6.589)	17.49 (5.918)	
Median	19.71	16.77	18.10	17.54	
Min, Max	8.4, 30.0	5.6, 30.0	4.8, 30.0	5.8, 29.8	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-reg-a.sas Date: 15:28/07AUG2023

Table 35.2.2.4.4.1.3a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	33	57	38	78	
Mean (StdDev)	17.70 (6.934)	14.71 (5.935)	15.38 (6.798)	14.07 (6.331)	
Median	18.14	13.31	15.46	13.64	
Min, Max	4.8, 29.8	2.8, 27.4	3.7, 29.8	3.1, 30.0	
C2D1 CFB					
n	33	57	38	78	
LS Mean (StdErr) [2]	-2.82 (0.557)	-3.49 (0.466)	-1.59 (0.731)	-3.13 (0.547)	
95% CI [2]	-3.93, -1.71	-4.42, -2.57	-3.04, -0.14	-4.21, -2.05	
Difference (95% CI) in CFB [2]		-0.67 (-1.94, 0.59)		-1.54 (-3.15, 0.07)	
p-value [3]		0.293		0.060	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-reg-a.sas Date: 15:28/07AUG2023

Table 35.2.2.4.4.1.3a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	33	56	38	77	
Mean (StdDev)	17.55 (7.569)	13.19 (6.142)	14.45 (7.161)	12.57 (6.490)	
Median	18.77	11.91	13.75	10.79	
Min, Max	4.5, 29.4	3.2, 25.4	1.4, 28.9	1.5, 30.0	
C3D1 CFB					
n	33	56	38	77	
LS Mean (StdErr) [2]	-2.57 (0.729)	-4.62 (0.611)	-2.40 (0.875)	-4.52 (0.655)	
95% CI [2]	-4.02, -1.12	-5.83, -3.40	-4.13, -0.67	-5.82, -3.23	
Difference (95% CI) in CFB [2]		-2.05 (-3.71, -0.39)		-2.12 (-4.06, -0.19)	
p-value [3]		0.016		0.031	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-reg-a.sas Date: 15:28/07AUG2023

Table 35.2.2.4.4.1.3a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	31	56	37	77	
Mean (StdDev)	16.93 (7.785)	12.15 (6.535)	14.50 (7.051)	11.73 (6.826)	
Median	18.42	11.64	14.21	9.86	
Min, Max	3.8, 29.6	0.7, 24.5	1.0, 29.7	0.7, 29.9	
C4D1 CFB					
n	31	56	37	77	
LS Mean (StdErr) [2]	-3.80 (0.902)	-5.93 (0.730)	-2.12 (0.946)	-5.24 (0.703)	
95% CI [2]	-5.59, -2.01	-7.38, -4.48	-4.00, -0.24	-6.63, -3.84	
Difference (95% CI) in CFB [2]		-2.13 (-4.14, -0.12)		-3.12 (-5.20, -1.03)	
p-value [3]		0.038		0.004	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-reg-a.sas Date: 15:28/07AUG2023

Table 35.2.2.4.4.1.3a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	30	57	37	78	
Mean (StdDev)	16.97 (8.501)	11.54 (6.366)	14.11 (6.919)	11.57 (6.816)	
Median	18.46	10.92	13.57	10.61	
Min, Max	1.7, 30.0	1.7, 25.2	1.5, 29.9	0.3, 30.0	
C5D1 CFB					
n	30	57	37	78	
LS Mean (StdErr) [2]	-3.88 (0.998)	-6.49 (0.779)	-2.49 (1.002)	-5.35 (0.741)	
95% CI [2]	-5.86, -1.89	-8.04, -4.94	-4.47, -0.50	-6.82, -3.88	
Difference (95% CI) in CFB [2]		-2.62 (-4.84, -0.39)		-2.86 (-5.06, -0.66)	
p-value [3]		0.022		0.011	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-reg-a.sas Date: 15:28/07AUG2023

Table 35.2.2.4.4.1.3a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	29	56	37	78	
Mean (StdDev)	16.45 (8.145)	11.20 (6.286)	14.02 (7.394)	11.01 (6.951)	
Median	17.20	10.57	13.07	10.29	
Min, Max	0.5, 30.0	1.0, 25.5	1.0, 29.6	0.1, 30.0	
C6D1 CFB					
n	29	56	37	78	
LS Mean (StdErr) [2]	-4.09 (1.034)	-6.76 (0.805)	-2.55 (1.064)	-5.89 (0.784)	
95% CI [2]	-6.15, -2.03	-8.36, -5.16	-4.66, -0.45	-7.44, -4.33	
Difference (95% CI) in CFB [2]		-2.67 (-4.99, -0.34)		-3.33 (-5.67, -1.00)	
p-value [3]		0.025		0.006	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-reg-a.sas Date: 15:28/07AUG2023

Table 35.2.2.4.4.1.3a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	30	55	36	76	
Mean (StdDev)	16.61 (8.336)	10.51 (6.039)	14.34 (6.799)	11.37 (6.914)	
Median	16.96	9.33	13.64	10.70	
Min, Max	0.5, 30.0	1.3, 24.1	2.7, 30.0	0.0, 30.0	
C7D1 CFB					
n	30	55	36	76	
LS Mean (StdErr) [2]	-3.99 (1.081)	-7.33 (0.868)	-2.08 (1.034)	-5.40 (0.757)	
95% CI [2]	-6.14, -1.84	-9.06, -5.60	-4.13, -0.03	-6.90, -3.90	
Difference (95% CI) in CFB [2]		-3.34 (-5.77, -0.92)		-3.32 (-5.60, -1.05)	
Hedges'G (95% CI) in CFB		-0.53 (-1.00, -0.08)		-0.51 (-0.93, -0.11)	
p-value [3]		0.008		0.005	
					0.995

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-reg-a.sas Date: 15:28/07AUG2023

Table 35.2.2.4.4.1.4a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-cou-a.sas Date: 15:29/07AUG2023

Table 35.2.2.4.4.1.4a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-cou-a.sas Date: 15:29/07AUG2023

Table 35.2.2.4.4.1.4a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-cou-a.sas Date: 15:29/07AUG2023

Table 35.2.2.4.4.1.4a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-cou-a.sas Date: 15:29/07AUG2023

Table 35.2.2.4.4.1.4a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-cou-a.sas Date: 15:29/07AUG2023

Table 35.2.2.4.4.1.5a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	26	52	45	87	
Mean (StdDev)	14.06 (5.912)	12.54 (4.248)	21.19 (5.118)	20.48 (4.883)	
Median	12.70	11.96	21.07	20.00	
Min, Max	4.8, 27.0	5.6, 22.8	11.1, 30.0	11.8, 30.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-ism-a.sas Date: 15:30/07AUG2023

Table 35.2.2.4.4.1.5a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	26	50	45	85	
Mean (StdDev)	12.21 (6.191)	10.08 (4.833)	18.92 (6.111)	16.85 (5.438)	
Median	10.46	9.54	18.14	16.69	
Min, Max	3.7, 26.5	2.8, 21.8	4.8, 29.8	7.9, 30.0	
C2D1 CFB					
n	26	50	45	85	
LS Mean (StdErr) [2]	-2.02 (0.706)	-2.53 (0.523)	-2.44 (0.623)	-3.93 (0.500)	
95% CI [2]	-3.43, -0.61	-3.58, -1.49	-3.67, -1.21	-4.92, -2.94	
Difference (95% CI) in CFB [2]		-0.52 (-2.07, 1.03)		-1.49 (-2.92, -0.06)	
p-value [3]		0.509		0.041	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-ism-a.sas Date: 15:30/07AUG2023

Table 35.2.2.4.4.1.5a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	26	50	45	83	
Mean (StdDev)	11.41 (6.952)	9.00 (4.590)	18.47 (6.521)	15.13 (6.132)	
Median	9.43	9.11	19.07	15.04	
Min, Max	1.4, 27.5	1.5, 20.7	5.9, 29.4	4.4, 30.0	
C3D1 CFB					
n	26	50	45	83	
LS Mean (StdErr) [2]	-2.83 (0.834)	-3.62 (0.617)	-2.60 (0.765)	-5.41 (0.617)	
95% CI [2]	-4.49, -1.16	-4.85, -2.39	-4.12, -1.09	-6.63, -4.19	
Difference (95% CI) in CFB [2]		-0.79 (-2.62, 1.04)		-2.81 (-4.57, -1.04)	
p-value [3]		0.390		0.002	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-ism-a.sas Date: 15:30/07AUG2023

Table 35.2.2.4.4.1.5a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	24	49	44	84	
Mean (StdDev)	11.13 (6.585)	8.18 (4.594)	18.05 (6.765)	14.07 (6.774)	
Median	8.67	7.31	18.74	14.07	
Min, Max	1.0, 25.5	0.7, 20.3	3.8, 29.7	0.7, 29.9	
C4D1 CFB					
n	24	49	44	84	
LS Mean (StdErr) [2]	-2.66 (0.861)	-4.16 (0.624)	-3.29 (0.898)	-6.62 (0.712)	
95% CI [2]	-4.38, -0.94	-5.41, -2.92	-5.07, -1.52	-8.03, -5.21	
Difference (95% CI) in CFB [2]		-1.51 (-3.41, 0.39)		-3.32 (-5.36, -1.28)	
p-value [3]		0.118		0.002	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-ism-a.sas Date: 15:30/07AUG2023

Table 35.2.2.4.4.1.5a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	51	44	84	
Mean (StdDev)	11.01 (6.996)	8.10 (4.445)	17.68 (7.162)	13.66 (6.835)	
Median	8.21	7.07	18.54	13.18	
Min, Max	1.5, 23.6	0.5, 19.0	1.7, 30.0	0.3, 30.0	
C5D1 CFB					
n	23	51	44	84	
LS Mean (StdErr) [2]	-2.88 (0.927)	-4.45 (0.646)	-3.69 (0.962)	-7.07 (0.762)	
95% CI [2]	-4.73, -1.03	-5.74, -3.16	-5.59, -1.79	-8.58, -5.56	
Difference (95% CI) in CFB [2]		-1.57 (-3.61, 0.47)		-3.38 (-5.56, -1.19)	
p-value [3]		0.129		0.003	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-ism-a.sas Date: 15:30/07AUG2023

Table 35.2.2.4.4.1.5a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	24	52	42	82	
Mean (StdDev)	11.23 (6.515)	7.78 (4.056)	17.29 (7.627)	13.19 (7.135)	
Median	10.75	7.29	17.59	13.14	
Min, Max	1.0, 22.9	0.1, 17.9	0.5, 30.0	0.7, 30.0	
C6D1 CFB					
n	24	52	42	82	
LS Mean (StdErr) [2]	-2.63 (0.933)	-4.73 (0.656)	-4.01 (1.044)	-7.62 (0.820)	
95% CI [2]	-4.49, -0.77	-6.04, -3.42	-6.07, -1.94	-9.24, -6.00	
Difference (95% CI) in CFB [2]		-2.10 (-4.15, -0.05)		-3.62 (-6.00, -1.23)	
p-value [3]		0.044		0.003	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-ism-a.sas Date: 15:30/07AUG2023

Table 35.2.2.4.4.1.5a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	23	51	43	80	
Mean (StdDev)	11.59 (5.928)	8.15 (4.268)	17.39 (7.621)	12.84 (7.099)	
Median	11.21	7.64	18.22	12.40	
Min, Max	2.7, 23.0	0.7, 19.1	0.5, 30.0	0.0, 30.0	
C7D1 CFB					
n	23	51	43	80	
LS Mean (StdErr) [2]	-2.47 (0.897)	-4.45 (0.625)	-3.84 (1.038)	-7.82 (0.836)	
95% CI [2]	-4.25, -0.68	-5.70, -3.21	-5.89, -1.78	-9.47, -6.16	
Difference (95% CI) in CFB [2]		-1.99 (-3.96, -0.01)		-3.98 (-6.35, -1.60)	
Hedges'G (95% CI) in CFB		-0.45 (-0.97, 0.05)		-0.55 (-0.94, -0.17)	
p-value [3]		0.048		0.001	
					0.259

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-ism-a.sas Date: 15:30/07AUG2023

Table 35.2.2.4.4.1.6a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	15	28	56	111	
Mean (StdDev)	17.42 (6.329)	17.72 (6.266)	18.89 (6.436)	17.46 (6.001)	
Median	18.64	17.88	18.93	16.93	
Min, Max	7.5, 26.7	7.1, 29.8	4.8, 30.0	5.6, 30.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-tryp-a.sas Date: 15:31/07AUG2023

Table 35.2.2.4.4.1.6a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	56	108	
Mean (StdDev)	13.43 (6.819)	14.95 (6.375)	17.27 (6.766)	14.19 (6.117)	
Median	11.86	14.42	16.79	13.50	
Min, Max	4.8, 24.9	5.2, 28.1	3.7, 29.8	2.8, 30.0	
C2D1 CFB					
n	15	27	56	108	
LS Mean (StdErr) [2]	-3.78 (1.152)	-2.82 (0.834)	-1.51 (0.468)	-3.18 (0.343)	
95% CI [2]	-6.11, -1.45	-4.51, -1.14	-2.44, -0.59	-3.86, -2.51	
Difference (95% CI) in CFB [2]		0.96 (-1.86, 3.78)		-1.67 (-2.80, -0.54)	
p-value [3]		0.494		0.004	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-tryp-a.sas Date: 15:31/07AUG2023

Table 35.2.2.4.4.1.6a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	27	56	106	
Mean (StdDev)	13.40 (7.212)	14.01 (6.413)	16.56 (7.452)	12.53 (6.304)	
Median	13.92	14.57	16.51	11.26	
Min, Max	3.8, 23.6	3.7, 27.1	1.4, 29.4	1.5, 30.0	
C3D1 CFB					
n	15	27	56	106	
LS Mean (StdErr) [2]	-3.94 (1.223)	-3.81 (0.885)	-2.17 (0.597)	-4.79 (0.440)	
95% CI [2]	-6.41, -1.47	-5.60, -2.02	-3.35, -0.99	-5.66, -3.93	
Difference (95% CI) in CFB [2]		0.13 (-2.86, 3.12)		-2.63 (-4.07, -1.18)	
p-value [3]		0.933		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-tryp-a.sas Date: 15:31/07AUG2023

Table 35.2.2.4.4.1.6a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	14	27	54	106	
Mean (StdDev)	12.59 (6.590)	13.19 (6.239)	16.39 (7.502)	11.58 (6.781)	
Median	10.93	13.23	17.39	9.71	
Min, Max	3.8, 23.0	2.2, 26.6	1.0, 29.7	0.7, 29.9	
C4D1 CFB					
n	14	27	54	106	
LS Mean (StdErr) [2]	-4.49 (1.357)	-4.49 (0.957)	-2.42 (0.685)	-5.77 (0.497)	
95% CI [2]	-7.24, -1.74	-6.43, -2.56	-3.77, -1.07	-6.76, -4.79	
Difference (95% CI) in CFB [2]		-0.01 (-3.31, 3.29)		-3.35 (-4.99, -1.71)	
p-value [3]		0.997		<0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-tryp-a.sas Date: 15:31/07AUG2023

Table 35.2.2.4.4.1.6a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	28	53	107	
Mean (StdDev)	11.57 (6.926)	12.83 (6.056)	16.40 (7.688)	11.23 (6.729)	
Median	9.86	12.77	15.92	10.00	
Min, Max	1.7, 22.4	2.4, 23.6	1.5, 30.0	0.3, 30.0	
C5D1 CFB					
n	14	28	53	107	
LS Mean (StdErr) [2]	-5.55 (1.508)	-4.77 (1.040)	-2.39 (0.729)	-6.04 (0.519)	
95% CI [2]	-8.59, -2.50	-6.88, -2.67	-3.83, -0.95	-7.06, -5.01	
Difference (95% CI) in CFB [2]		0.77 (-2.88, 4.42)		-3.64 (-5.38, -1.91)	
p-value [3]		0.671		<0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-tryp-a.sas Date: 15:31/07AUG2023

Table 35.2.2.4.4.1.6a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	28	52	106	
Mean (StdDev)	11.23 (6.507)	12.54 (6.351)	16.13 (7.806)	10.71 (6.712)	
Median	9.18	11.57	16.33	9.94	
Min, Max	0.5, 22.5	2.3, 29.6	1.0, 30.0	0.1, 30.0	
C6D1 CFB					
n	14	28	52	106	
LS Mean (StdErr) [2]	-5.79 (1.560)	-5.03 (1.076)	-2.47 (0.773)	-6.52 (0.548)	
95% CI [2]	-8.95, -2.64	-7.21, -2.85	-3.99, -0.94	-7.60, -5.44	
Difference (95% CI) in CFB [2]		0.76 (-3.02, 4.54)		-4.05 (-5.90, -2.21)	
p-value [3]		0.686		<0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-tryp-a.sas Date: 15:31/07AUG2023

Table 35.2.2.4.4.1.6a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	14	27	52	104	
Mean (StdDev)	12.14 (6.710)	12.21 (6.356)	16.24 (7.602)	10.70 (6.594)	
Median	11.75	11.69	16.62	9.80	
Min, Max	0.5, 22.6	2.8, 29.0	2.7, 30.0	0.0, 30.0	
C7D1 CFB					
n	14	27	52	104	
LS Mean (StdErr) [2]	-4.90 (1.617)	-5.22 (1.132)	-2.43 (0.766)	-6.45 (0.547)	
95% CI [2]	-8.17, -1.63	-7.52, -2.93	-3.94, -0.91	-7.53, -5.37	
Difference (95% CI) in CFB [2]		-0.32 (-4.28, 3.63)		-4.02 (-5.85, -2.19)	
Hedges'G (95% CI) in CFB		-0.05 (-0.72, 0.61)		-0.72 (-1.08, -0.39)	
p-value [3]		0.869		<0.0001	
					0.083

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-tryp-a.sas Date: 15:31/07AUG2023

Table 35.2.2.4.4.1.7a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	67	129	4	10	
Mean (StdDev)	18.76 (6.355)	17.36 (5.965)	15.57 (7.324)	19.44 (6.909)	
Median	18.79	16.93	14.39	19.96	
Min, Max	4.8, 30.0	5.6, 30.0	8.1, 25.4	6.2, 29.6	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-ecog-a.sas Date: 15:31/07AUG2023

Table 35.2.2.4.4.1.7a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	67	125	4	10	
Mean (StdDev)	16.58 (7.025)	14.20 (5.991)	14.55 (4.875)	16.10 (8.087)	
Median	16.57	13.38	13.89	15.08	
Min, Max	3.7, 29.8	2.8, 28.1	9.9, 20.6	4.1, 30.0	
C2D1 CFB					
n	67	125	4	10	
LS Mean (StdErr) [2]	-2.23 (0.478)	-3.30 (0.377)	1.60 (3.661)	-1.05 (2.803)	
95% CI [2]	-3.17, -1.29	-4.04, -2.56	-6.56, 9.75	-7.29, 5.20	
Difference (95% CI) in CFB [2]		-1.07 (-2.14, 0.00)		-2.64 (-9.42, 4.13)	
p-value [3]		0.050		0.405	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-ecog-a.sas Date: 15:31/07AUG2023

Table 35.2.2.4.4.1.7a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	67	123	4	10	
Mean (StdDev)	16.03 (7.624)	12.66 (6.085)	13.61 (3.775)	14.94 (8.960)	
Median	16.21	11.36	14.57	14.50	
Min, Max	1.4, 29.4	2.6, 27.1	8.6, 16.7	1.5, 30.0	
C3D1 CFB					
n	67	123	4	10	
LS Mean (StdErr) [2]	-2.53 (0.584)	-4.62 (0.460)	1.66 (4.448)	-1.37 (3.406)	
95% CI [2]	-3.68, -1.38	-5.52, -3.71	-8.25, 11.57	-8.96, 6.22	
Difference (95% CI) in CFB [2]		-2.09 (-3.40, -0.78)		-3.03 (-11.26, 5.20)	
p-value [3]		0.002		0.431	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-ecog-a.sas Date: 15:31/07AUG2023

Table 35.2.2.4.4.1.7a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	64	123	4	10	
Mean (StdDev)	15.71 (7.626)	11.77 (6.409)	14.00 (3.348)	13.56 (9.748)	
Median	16.15	10.71	13.11	10.56	
Min, Max	1.0, 29.7	0.7, 26.6	11.0, 18.8	0.7, 29.9	
C4D1 CFB					
n	64	123	4	10	
LS Mean (StdErr) [2]	-2.95 (0.661)	-5.53 (0.510)	2.92 (5.295)	-1.95 (4.054)	
95% CI [2]	-4.25, -1.64	-6.54, -4.52	-8.88, 14.72	-10.98, 7.09	
Difference (95% CI) in CFB [2]		-2.58 (-4.05, -1.11)		-4.87 (-14.67, 4.93)	
p-value [3]		<0.001		0.294	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-ecog-a.sas Date: 15:31/07AUG2023

Table 35.2.2.4.4.1.7a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	63	125	4	10	
Mean (StdDev)	15.63 (7.870)	11.23 (6.137)	11.65 (4.308)	15.69 (10.507)	
Median	16.15	10.50	12.79	18.40	
Min, Max	1.5, 30.0	0.3, 25.2	5.5, 15.5	0.5, 30.0	
C5D1 CFB					
n	63	125	4	10	
LS Mean (StdErr) [2]	-3.08 (0.693)	-6.08 (0.524)	2.56 (6.057)	1.70 (4.637)	
95% CI [2]	-4.45, -1.71	-7.11, -5.04	-10.94, 16.05	-8.63, 12.04	
Difference (95% CI) in CFB [2]		-3.00 (-4.54, -1.46)		-0.85 (-12.06, 10.35)	
p-value [3]		<0.001		0.869	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-ecog-a.sas Date: 15:31/07AUG2023

Table 35.2.2.4.4.1.7a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	62	124	4	10	
Mean (StdDev)	15.27 (7.969)	10.83 (6.280)	12.27 (2.226)	14.26 (10.196)	
Median	16.08	10.36	13.04	11.50	
Min, Max	0.5, 30.0	0.7, 29.6	9.0, 14.0	0.1, 30.0	
C6D1 CFB					
n	62	124	4	10	
LS Mean (StdErr) [2]	-3.24 (0.754)	-6.42 (0.569)	3.06 (5.171)	0.35 (3.959)	
95% CI [2]	-4.73, -1.75	-7.54, -5.30	-8.46, 14.58	-8.47, 9.17	
Difference (95% CI) in CFB [2]		-3.18 (-4.86, -1.49)		-2.71 (-12.28, 6.86)	
p-value [3]		<0.001		0.542	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-ecog-a.sas Date: 15:31/07AUG2023

Table 35.2.2.4.4.1.7a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	63	121	3	10	
Mean (StdDev)	15.44 (7.719)	10.77 (6.193)	13.81 (2.837)	13.89 (9.920)	
Median	16.14	10.36	12.86	11.61	
Min, Max	0.5, 30.0	0.0, 29.0	11.6, 17.0	0.7, 30.0	
C7D1 CFB					
n	63	121	3	10	
LS Mean (StdErr) [2]	-3.00 (0.743)	-6.35 (0.570)	3.73 (6.191)	-0.24 (4.331)	
95% CI [2]	-4.46, -1.53	-7.47, -5.22	-10.27, 17.74	-10.04, 9.56	
Difference (95% CI) in CFB [2]		-3.35 (-5.01, -1.68)		-3.97 (-15.53, 7.58)	
Hedges'G (95% CI) in CFB		-0.54 (-0.86, -0.24)		-0.28 (-1.80, 1.11)	
p-value [3]		<0.001		0.457	
					0.887

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-ecog-a.sas Date: 15:31/07AUG2023

Table 35.2.2.4.4.1.8a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	67	129	
Mean (StdDev)	18.38 (8.486)	21.37 (6.779)	18.59 (6.335)	17.21 (5.896)	
Median	19.86	21.68	18.64	16.43	
Min, Max	6.8, 27.0	8.8, 29.6	4.8, 30.0	5.6, 30.0	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-thpy-a.sas Date: 15:32/07AUG2023

Table 35.2.2.4.4.1.8a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	67	125	
Mean (StdDev)	16.73 (8.504)	18.19 (5.754)	16.45 (6.883)	14.03 (6.100)	
Median	16.32	17.52	16.43	13.31	
Min, Max	7.8, 26.5	8.0, 25.9	3.7, 29.8	2.8, 30.0	
C2D1 CFB					
n	4	10	67	125	
LS Mean (StdErr) [2]	-1.90 (2.115)	-2.34 (2.115)	-2.15 (0.494)	-3.28 (0.388)	
95% CI [2]	-6.61, 2.81	-7.05, 2.37	-3.13, -1.18	-4.05, -2.52	
Difference (95% CI) in CFB [2]		-0.44 (-6.43, 5.55)		-1.13 (-2.23, -0.03)	
p-value [3]		0.874		0.044	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-thpy-a.sas Date: 15:32/07AUG2023

Table 35.2.2.4.4.1.8a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	8	67	125	
Mean (StdDev)	15.61 (7.266)	16.64 (6.134)	15.91 (7.530)	12.59 (6.287)	
Median	17.71	16.45	16.21	11.36	
Min, Max	5.8, 21.2	8.5, 25.0	1.4, 29.4	1.5, 30.0	
C3D1 CFB					
n	4	8	67	125	
LS Mean (StdErr) [2]	-2.30 (3.408)	-4.42 (3.408)	-2.47 (0.592)	-4.51 (0.465)	
95% CI [2]	-10.16, 5.56	-12.28, 3.44	-3.64, -1.30	-5.43, -3.60	
Difference (95% CI) in CFB [2]		-2.11 (-12.17, 7.94)		-2.04 (-3.36, -0.73)	
p-value [3]		0.641		0.002	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-thpy-a.sas Date: 15:32/07AUG2023

Table 35.2.2.4.4.1.8a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	4	9	64	124	
Mean (StdDev)	14.24 (8.728)	14.05 (6.532)	15.69 (7.423)	11.75 (6.693)	
Median	14.87	12.79	15.61	10.57	
Min, Max	5.1, 22.2	6.6, 24.6	1.0, 29.7	0.7, 29.9	
C4D1 CFB					
n	4	9	64	124	
LS Mean (StdErr) [2]	-4.54 (3.561)	-7.04 (3.561)	-2.70 (0.676)	-5.30 (0.519)	
95% CI [2]	-12.59, 3.52	-15.09, 1.02	-4.04, -1.37	-6.32, -4.28	
Difference (95% CI) in CFB [2]		-2.50 (-12.77, 7.77)		-2.60 (-4.08, -1.11)	
p-value [3]		0.595		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-thpy-a.sas Date: 15:32/07AUG2023

Table 35.2.2.4.4.1.8a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	9	63	126	
Mean (StdDev)	13.58 (9.852)	12.55 (6.631)	15.51 (7.673)	11.49 (6.625)	
Median	14.08	10.36	15.54	10.71	
Min, Max	3.4, 22.8	6.8, 24.5	1.5, 30.0	0.3, 30.0	
C5D1 CFB					
n	4	9	63	126	
LS Mean (StdErr) [2]	-5.87 (3.430)	-9.41 (3.430)	-2.91 (0.725)	-5.52 (0.547)	
95% CI [2]	-13.63, 1.89	-17.17, -1.65	-4.34, -1.48	-6.60, -4.44	
Difference (95% CI) in CFB [2]		-3.54 (-13.44, 6.35)		-2.61 (-4.21, -1.02)	
p-value [3]		0.439		0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-thpy-a.sas Date: 15:32/07AUG2023

Table 35.2.2.4.4.1.8a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	62	125	
Mean (StdDev)	12.28 (9.777)	11.63 (6.173)	15.27 (7.684)	11.05 (6.712)	
Median	13.36	10.36	15.55	10.38	
Min, Max	1.7, 20.7	5.8, 23.4	0.5, 30.0	0.1, 30.0	
C6D1 CFB					
n	4	9	62	125	
LS Mean (StdErr) [2]	-7.12 (3.516)	-10.36 (3.516)	-2.93 (0.765)	-5.91 (0.575)	
95% CI [2]	-15.08, 0.83	-18.31, -2.41	-4.44, -1.42	-7.04, -4.77	
Difference (95% CI) in CFB [2]		-3.23 (-13.38, 6.91)		-2.97 (-4.66, -1.28)	
p-value [3]		0.489		<0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-thpy-a.sas Date: 15:32/07AUG2023

Table 35.2.2.4.4.1.8a
Change from Baseline of Lead (Most Severe) Domains and Neurocognitive Symptom Cluster of the ISM-SAF by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	9	62	122	
Mean (StdDev)	12.95 (9.553)	12.70 (6.237)	15.52 (7.487)	10.89 (6.580)	
Median	13.82	10.31	15.57	10.39	
Min, Max	2.7, 21.5	5.2, 24.7	0.5, 30.0	0.0, 30.0	
C7D1 CFB					
n	4	9	62	122	
LS Mean (StdErr) [2]	-6.34 (3.875)	-8.87 (3.875)	-2.67 (0.761)	-5.94 (0.578)	
95% CI [2]	-15.11, 2.43	-17.64, -0.11	-4.18, -1.17	-7.08, -4.80	
Difference (95% CI) in CFB [2]		-2.53 (-13.71, 8.64)		-3.27 (-4.95, -1.58)	
Hedges'G (95% CI) in CFB		-0.22 (-1.60, 1.06)		-0.52 (-0.84, -0.21)	
p-value [3]		0.620		<0.001	
					0.908

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note1: The "lead domain/symptom cluster" score refers to the domain/symptom cluster with highest score at Baseline in each patient. If patient has tie with multiple lead domain/symptom clusters, the average of change from baseline is used for the summary.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-lead-sym-dom-sum-g-itt-thpy-a.sas Date: 15:32/07AUG2023

Table 35.2.1.3.1.1a
Summary of Patients with >=30% Reduction in ISM-SAF TSS at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=30% Reduction in TSS at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	21/ 71 (29.6) (19.3, 41.6)	64/141 (45.4) (37.0, 54.0)	2.07 (1.08, 3.99) 0.020	1.57 (1.05, 2.36) 0.028	0.17 (0.03, 0.30) 0.014	
Age Group (Years)						0.064
< 65	20/ 60 (33.3) (21.7, 46.7)	58/132 (43.9) (35.3, 52.8)	1.65 (0.83, 3.30) 0.127	1.36 (0.90, 2.05) 0.142	0.12 (-0.03, 0.27) 0.113	
>= 65	1/ 11 (9.1) (0.2, 41.3)	6/ 9 (66.7) (29.9, 92.5)	11.33 (0.74, 570.27) 0.032	7.89 (0.49, 127.50) 0.146	0.50 (0.08, 0.93) 0.020	

Abbreviations: TSS = total symptom score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-resp-itt-a.sas Date: 17:59/13APR2023

Table 35.2.1.3.1.1a
Summary of Patients with >=30% Reduction in ISM-SAF TSS at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=30% Reduction in TSS at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Sex						0.119
Male	7/ 17 (41.2) (18.4, 67.1)	16/ 41 (39.0) (24.2, 55.5)	0.93 (0.26, 3.44) 0.906	0.96 (0.49, 1.89) >0.999	-0.02 (-0.29, 0.26) 0.903	
Female	14/ 54 (25.9) (15.0, 39.7)	48/100 (48.0) (37.9, 58.2)	2.80 (1.27, 6.20) 0.005	1.92 (1.16, 3.18) 0.011	0.24 (0.08, 0.39) 0.003	
Region						0.705
North America	9/ 33 (27.3) (13.3, 45.5)	27/ 60 (45.0) (32.1, 58.4)	2.42 (0.84, 7.02) 0.075	1.73 (0.91, 3.27) 0.094	0.19 (-0.00, 0.39) 0.056	
Europe	12/ 38 (31.6) (17.5, 48.7)	37/ 81 (45.7) (34.6, 57.1)	1.89 (0.77, 4.69) 0.132	1.46 (0.87, 2.45) 0.152	0.14 (-0.04, 0.32) 0.115	

Abbreviations: TSS = total symptom score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-resp-itt-a.sas Date: 17:59/13APR2023

Table 35.2.1.3.1.1a
Summary of Patients with >=30% Reduction in ISM-SAF TSS at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=30% Reduction in TSS at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country						0.959
BEL	1/ 1 (100.0) (2.5, 100.0)	1/ 3 (33.3) (0.8, 90.6)	0.00 (0.00, 19.00) 0.317	0.00 (NE, NE) NE	-1.00 (-1.00, -1.00) NE	
CAN	1/ 5 (20.0) (0.5, 71.6)	6/ 8 (75.0) (34.9, 96.8)	NE (0.52, NE) 0.059	3.50 (0.69, 17.84) 0.132	0.60 (0.20, 1.00) 0.004	
CHE	0/ 1 (0.0) (0.0, 97.5)	1/ 2 (50.0) (1.3, 98.7)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DEU	4/ 15 (26.7) (7.8, 55.1)	7/ 19 (36.8) (16.3, 61.6)	1.57 (0.28, 9.37) 0.566	1.35 (0.49, 3.68) 0.559	0.10 (-0.22, 0.41) 0.551	
DNK	0/0	1/ 1 (100.0) (2.5, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: TSS = total symptom score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-resp-itt-a.sas Date: 17:59/13APR2023

Table 35.2.1.3.1.1a
Summary of Patients with >=30% Reduction in ISM-SAF TSS at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=30% Reduction in TSS at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
ESP	1/ 3 (33.3) (0.8, 90.6)	9/ 14 (64.3) (35.1, 87.2)	4.86 (0.20, 294.60) 0.215	2.29 (0.39, 13.43) 0.360	0.41 (-0.20, 1.00) 0.189	
FRA	2/ 6 (33.3) (4.3, 77.7)	5/ 11 (45.5) (16.7, 76.6)	1.88 (0.18, 29.62) 0.492	1.88 (0.21, 16.53) 0.571	0.22 (-0.41, 0.85) 0.496	
GBR	1/ 5 (20.0) (0.5, 71.6)	6/ 11 (54.5) (23.4, 83.3)	6.30 (0.29, 339.99) 0.203	3.12 (0.43, 22.41) 0.258	0.39 (-0.08, 0.86) 0.105	
ITA	0/0	0/ 4 (0.0) (0.0, 60.2)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: TSS = total symptom score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-resp-itt-a.sas Date: 17:59/13APR2023

Table 35.2.1.3.1.1a
Summary of Patients with >=30% Reduction in ISM-SAF TSS at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=30% Reduction in TSS at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
NLD	1/ 3 (33.3) (0.8, 90.6)	4/ 9 (44.4) (13.7, 78.8)	1.00 (0.01, 117.33) >0.999	1.00 (0.10, 9.61) >0.999	0.00 (-0.75, 0.75) >0.999	
NOR	2/ 3 (66.7) (9.4, 99.2)	2/ 5 (40.0) (5.3, 85.3)	0.46 (0.01, 12.54) 0.541	0.63 (0.15, 2.65) >0.999	-0.25 (-1.00, 0.54) 0.536	
SWE	0/ 1 (0.0) (0.0, 97.5)	1/ 2 (50.0) (1.3, 98.7)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
USA	8/ 28 (28.6) (13.2, 48.7)	21/ 52 (40.4) (27.0, 54.9)	1.86 (0.61, 5.72) 0.243	1.49 (0.75, 2.99) 0.258	0.14 (-0.08, 0.35) 0.215	

Abbreviations: TSS = total symptom score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-resp-itt-a.sas Date: 17:59/13APR2023

Table 35.2.1.3.1.1a
Summary of Patients with >=30% Reduction in ISM-SAF TSS at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=30% Reduction in TSS at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Baseline ISM Status						0.678
Moderate	6/ 26 (23.1) (9.0, 43.6)	22/ 52 (42.3) (28.7, 56.8)	2.50 (0.78, 8.84) 0.090	1.86 (0.86, 4.00) 0.114	0.20 (-0.01, 0.41) 0.066	
Severe	15/ 45 (33.3) (20.0, 49.0)	42/ 87 (48.3) (37.4, 59.2)	1.88 (0.84, 4.28) 0.100	1.46 (0.91, 2.35) 0.120	0.15 (-0.02, 0.32) 0.088	
Baseline Serum Tryptase (ng/mL)						0.233
< 20	6/ 15 (40.0) (16.3, 67.7)	11/ 28 (39.3) (21.5, 59.4)	1.06 (0.25, 4.85) 0.928	1.04 (0.47, 2.27) 0.927	0.01 (-0.29, 0.32) 0.926	
>= 20	15/ 56 (26.8) (15.8, 40.3)	53/113 (46.9) (37.5, 56.5)	2.49 (1.17, 5.35) 0.010	1.77 (1.10, 2.85) 0.018	0.21 (0.06, 0.36) 0.006	

Abbreviations: TSS = total symptom score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-resp-itt-a.sas Date: 17:59/13APR2023

Table 35.2.1.3.1.1a
Summary of Patients with >=30% Reduction in ISM-SAF TSS at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=30% Reduction in TSS at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.950
0 or 1	20/ 67 (29.9) (19.3, 42.3)	60/131 (45.8) (37.1, 54.7)	2.10 (1.07, 4.15) 0.021	1.58 (1.05, 2.40) 0.030	0.17 (0.03, 0.31) 0.015	
2+	1/ 4 (25.0) (0.6, 80.6)	4/ 10 (40.0) (12.2, 73.8)	2.10 (0.13, 137.53) 0.529	1.73 (0.30, 10.15) 0.542	0.20 (-0.40, 0.81) 0.510	
Prior TKI therapy						0.715
Yes	2/ 4 (50.0) (6.8, 93.2)	6/ 10 (60.0) (26.2, 87.8)	1.50 (0.02, 117.66) 0.808	1.17 (0.27, 5.09) 0.838	0.08 (-0.49, 0.65) 0.795	
No	19/ 67 (28.4) (18.0, 40.7)	58/131 (44.3) (35.6, 53.2)	2.09 (1.06, 4.15) 0.023	1.60 (1.04, 2.46) 0.032	0.17 (0.03, 0.31) 0.017	

Abbreviations: TSS = total symptom score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-resp-itt-a.sas Date: 17:59/13APR2023

Table 35.2.1.3.2.1a
Proportion of Patients with >=50% Reduction in TSS of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=50% Reduction in TSS at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	7/ 71 (9.9) (4.1, 19.3)	35/141 (24.8) (17.9, 32.8)	3.10 (1.24, 8.64) 0.009	2.56 (1.19, 5.48) 0.016	0.15 (0.05, 0.25) 0.003	
Age Group (Years)						0.977
< 65	7/ 60 (11.7) (4.8, 22.6)	31/132 (23.5) (16.5, 31.6)	2.36 (0.92, 6.68) 0.057	2.02 (0.94, 4.35) 0.071	0.12 (0.01, 0.23) 0.032	
>= 65	0/ 11 (0.0) (0.0, 28.5)	4/ 9 (44.4) (13.7, 78.8)	NE (0.82, NE) 0.044	NE (NE, NE) NE	0.41 (0.06, 0.77) 0.021	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-resp2-itt-a.sas Date: 17:59/13APR2023

Table 35.2.1.3.2.1a
Proportion of Patients with >=50% Reduction in TSS of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=50% Reduction in TSS at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Sex						0.477
Male	2/ 17 (11.8) (1.5, 36.4)	8/ 41 (19.5) (8.8, 34.9)	1.84 (0.30, 19.19) 0.489	1.65 (0.39, 6.89) 0.493	0.08 (-0.12, 0.27) 0.437	
Female	5/ 54 (9.3) (3.1, 20.3)	27/100 (27.0) (18.6, 36.8)	3.73 (1.28, 13.15) 0.008	2.99 (1.22, 7.35) 0.017	0.18 (0.07, 0.30) 0.002	
Region						0.514
North America	4/ 33 (12.1) (3.4, 28.2)	14/ 60 (23.3) (13.4, 36.0)	2.29 (0.61, 10.20) 0.188	1.97 (0.70, 5.59) 0.201	0.12 (-0.04, 0.28) 0.146	
Europe	3/ 38 (7.9) (1.7, 21.4)	21/ 81 (25.9) (16.8, 36.9)	4.39 (1.11, 23.88) 0.020	3.28 (1.06, 10.12) 0.039	0.18 (0.06, 0.31) 0.005	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-resp2-itt-a.sas Date: 17:59/13APR2023

Table 35.2.1.3.2.1a
Proportion of Patients with >=50% Reduction in TSS of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=50% Reduction in TSS at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country						>0.999
BEL	0/ 1 (0.0) (0.0, 97.5)	0/ 3 (0.0) (0.0, 70.8)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
CAN	0/ 5 (0.0) (0.0, 52.2)	3/ 8 (37.5) (8.5, 75.5)	NE (0.28, NE) 0.109	NE (NE, NE) NE	0.44 (0.06, 0.82) 0.021	
CHE	0/ 1 (0.0) (0.0, 97.5)	1/ 2 (50.0) (1.3, 98.7)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DEU	1/ 15 (6.7) (0.2, 31.9)	4/ 19 (21.1) (6.1, 45.6)	3.05 (0.26, 170.51) 0.315	2.68 (0.34, 20.75) 0.346	0.12 (-0.10, 0.35) 0.285	
DNK	0/0	1/ 1 (100.0) (2.5, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-resp2-itt-a.sas Date: 17:59/13APR2023

Table 35.2.1.3.2.1a
Proportion of Patients with >=50% Reduction in TSS of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=50% Reduction in TSS at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
ESP	0/ 3 (0.0) (0.0, 70.8)	6/ 14 (42.9) (17.7, 71.1)	NE (0.39, NE) 0.143	NE (NE, NE) NE	0.50 (0.21, 0.79) <0.001	
FRA	1/ 6 (16.7) (0.4, 64.1)	2/ 11 (18.2) (2.3, 51.8)	1.25 (0.04, 90.25) 0.894	1.25 (0.04, 38.86) 0.899	0.03 (-0.38, 0.44) 0.881	
GBR	0/ 5 (0.0) (0.0, 52.2)	2/ 11 (18.2) (2.3, 51.8)	NE (0.13, NE) 0.312	NE (NE, NE) NE	0.21 (-0.07, 0.50) 0.144	
ITA	0/0	0/ 4 (0.0) (0.0, 60.2)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-resp2-itt-a.sas Date: 17:59/13APR2023

Table 35.2.1.3.2.1a
Proportion of Patients with >=50% Reduction in TSS of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=50% Reduction in TSS at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
NLD	0/ 3 (0.0) (0.0, 70.8)	3/ 9 (33.3) (7.5, 70.1)	NE (0.05, NE) 0.317	NE (NE, NE) NE	0.33 (-0.20, 0.87) 0.221	
NOR	1/ 3 (33.3) (0.8, 90.6)	1/ 5 (20.0) (0.5, 71.6)	0.50 (0.00, 78.17) 0.739	0.67 (0.08, 5.54) >0.999	-0.11 (-0.69, 0.47) 0.717	
SWE	0/ 1 (0.0) (0.0, 97.5)	1/ 2 (50.0) (1.3, 98.7)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
USA	4/ 28 (14.3) (4.0, 32.7)	11/ 52 (21.2) (11.1, 34.7)	1.90 (0.46, 8.92) 0.346	1.66 (0.58, 4.81) 0.347	0.09 (-0.08, 0.26) 0.299	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-resp2-itt-a.sas Date: 17:59/13APR2023

Table 35.2.1.3.2.1a
Proportion of Patients with >=50% Reduction in TSS of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=50% Reduction in TSS at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Baseline ISM Status						0.503
Moderate	2/ 26 (7.7) (0.9, 25.1)	14/ 52 (26.9) (15.6, 41.0)	4.84 (0.92, 45.95) 0.041	3.69 (0.90, 15.16) 0.070	0.20 (0.04, 0.36) 0.012	
Severe	5/ 45 (11.1) (3.7, 24.1)	21/ 87 (24.1) (15.6, 34.5)	2.47 (0.81, 8.97) 0.088	2.11 (0.85, 5.25) 0.107	0.12 (-0.00, 0.25) 0.058	
Baseline Serum Tryptase (ng/mL)						0.789
< 20	1/ 15 (6.7) (0.2, 31.9)	4/ 28 (14.3) (4.0, 32.7)	2.39 (0.19, 121.38) 0.474	2.22 (0.23, 21.01) 0.487	0.08 (-0.10, 0.26) 0.410	
>= 20	6/ 56 (10.7) (4.0, 21.9)	31/113 (27.4) (19.5, 36.6)	3.22 (1.20, 10.03) 0.012	2.61 (1.16, 5.87) 0.021	0.17 (0.06, 0.29) 0.004	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-resp2-itt-a.sas Date: 17:59/13APR2023

Table 35.2.1.3.2.1a
Proportion of Patients with >=50% Reduction in TSS of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=50% Reduction in TSS at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.972
0 or 1	7/ 67 (10.4) (4.3, 20.3)	33/131 (25.2) (18.0, 33.5)	2.97 (1.17, 8.31) 0.014	2.45 (1.14, 5.25) 0.022	0.15 (0.05, 0.26) 0.005	
2+	0/ 4 (0.0) (0.0, 60.2)	2/ 10 (20.0) (2.5, 55.6)	NE (0.14, NE) 0.320	NE (NE, NE) NE	0.24 (-0.04, 0.52) 0.096	
Prior TKI therapy						0.294
Yes	1/ 4 (25.0) (0.6, 80.6)	2/ 10 (20.0) (2.5, 55.6)	1.38 (0.04, 103.58) 0.867	1.38 (0.03, 57.40) 0.867	0.06 (-0.49, 0.60) 0.839	
No	6/ 67 (9.0) (3.4, 18.5)	33/131 (25.2) (18.0, 33.5)	3.49 (1.32, 10.72) 0.006	2.86 (1.25, 6.56) 0.013	0.16 (0.06, 0.27) 0.001	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-resp2-itt-a.sas Date: 17:59/13APR2023

Table 35.2.1.3.3.1a
Proportion of Patients with >=16.5 Points Reduction in TSS of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=16.5 Point Reduction in TSS at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	19/ 71 (26.8) (16.9, 38.6)	54/141 (38.3) (30.2, 46.9)	1.81 (0.91, 3.76) 0.068	1.47 (0.94, 2.27) 0.088	0.12 (-0.01, 0.25) 0.060	
Age Group (Years)						0.970
< 65	19/ 60 (31.7) (20.3, 45.0)	49/132 (37.1) (28.9, 46.0)	1.44 (0.70, 3.04) 0.283	1.26 (0.81, 1.95) 0.306	0.08 (-0.06, 0.22) 0.275	
>= 65	0/ 11 (0.0) (0.0, 28.5)	5/ 9 (55.6) (21.2, 86.3)	NE (1.19, NE) 0.020	NE (NE, NE) NE	0.50 (0.13, 0.87) 0.008	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-resp3-itt-a.sas Date: 18:00/13APR2023

Table 35.2.1.3.3.1a
Proportion of Patients with >=16.5 Points Reduction in TSS of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=16.5 Point Reduction in TSS at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Sex						0.076
Male	6/ 17 (35.3) (14.2, 61.7)	11/ 41 (26.8) (14.2, 42.9)	0.68 (0.16, 2.91) 0.532	0.77 (0.34, 1.75) >0.999	-0.08 (-0.34, 0.18) 0.545	
Female	13/ 54 (24.1) (13.5, 37.6)	43/100 (43.0) (33.1, 53.3)	2.66 (1.16, 6.34) 0.012	1.85 (1.09, 3.12) 0.022	0.20 (0.05, 0.34) 0.007	
Region						0.644
North America	10/ 33 (30.3) (15.6, 48.7)	23/ 60 (38.3) (26.1, 51.8)	1.51 (0.53, 4.52) 0.398	1.30 (0.69, 2.46) 0.422	0.09 (-0.11, 0.29) 0.390	
Europe	9/ 38 (23.7) (11.4, 40.2)	31/ 81 (38.3) (27.7, 49.7)	2.19 (0.82, 6.28) 0.088	1.65 (0.89, 3.05) 0.113	0.15 (-0.01, 0.32) 0.070	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-resp3-itt-a.sas Date: 18:00/13APR2023

Table 35.2.1.3.3.1a
Proportion of Patients with >=16.5 Points Reduction in TSS of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=16.5 Point Reduction in TSS at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country						>0.999
BEL	1/ 1 (100.0) (2.5, 100.0)	0/ 3 (0.0) (0.0, 70.8)	0.00 (0.00, 19.00) 0.317	0.00 (NE, NE) NE	-1.00 (-1.00, -1.00) NE	
CAN	1/ 5 (20.0) (0.5, 71.6)	4/ 8 (50.0) (15.7, 84.3)	2.17 (0.11, 176.61) 0.473	2.17 (0.23, 20.60) 0.501	0.28 (-0.49, 1.00) 0.474	
CHE	0/ 1 (0.0) (0.0, 97.5)	1/ 2 (50.0) (1.3, 98.7)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DEU	5/ 15 (33.3) (11.8, 61.6)	9/ 19 (47.4) (24.4, 71.1)	1.94 (0.35, 11.45) 0.401	1.44 (0.61, 3.42) 0.410	0.14 (-0.17, 0.45) 0.377	
DNK	0/0	1/ 1 (100.0) (2.5, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-resp3-itt-a.sas Date: 18:00/13APR2023

Table 35.2.1.3.3.1a
Proportion of Patients with >=16.5 Points Reduction in TSS of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=16.5 Point Reduction in TSS at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
ESP	0/ 3 (0.0) (0.0, 70.8)	8/ 14 (57.1) (28.9, 82.3)	NE (0.74, NE) 0.042	NE (NE, NE) NE	0.58 (0.26, 0.89) <0.001	
FRA	0/ 6 (0.0) (0.0, 45.9)	4/ 11 (36.4) (10.9, 69.2)	NE (0.31, NE) 0.127	NE (NE, NE) NE	0.31 (-0.05, 0.67) 0.087	
GBR	1/ 5 (20.0) (0.5, 71.6)	4/ 11 (36.4) (10.9, 69.2)	2.60 (0.12, 166.69) 0.528	1.96 (0.25, 15.62) 0.525	0.18 (-0.29, 0.64) 0.457	
ITA	0/0	0/ 4 (0.0) (0.0, 60.2)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-resp3-itt-a.sas Date: 18:00/13APR2023

Table 35.2.1.3.3.1a
Proportion of Patients with >=16.5 Points Reduction in TSS of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=16.5 Point Reduction in TSS at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
NLD	0/ 3 (0.0)	3/ 9 (33.3)	NE	NE	0.33	
	(0.0, 70.8)	(7.5, 70.1)	(0.05, NE)	(NE, NE)	(-0.20, 0.87)	
			0.317	NE	0.221	
NOR	1/ 3 (33.3)	0/ 5 (0.0)	0.00	0.00	-0.36	
	(0.8, 90.6)	(0.0, 52.2)	(0.00, 9.50)	(NE, NE)	(-0.89, 0.18)	
			0.157	NE	0.189	
SWE	1/ 1 (100.0)	1/ 2 (50.0)	NE	NE	NE	
	(2.5, 100.0)	(1.3, 98.7)	(NE, NE)	(NE, NE)	(NE, NE)	
			NE	NE	NE	
USA	9/ 28 (32.1)	19/ 52 (36.5)	1.46	1.26	0.08	
	(15.9, 52.4)	(23.6, 51.0)	(0.46, 4.77)	(0.65, 2.44)	(-0.13, 0.29)	
			0.484	0.497	0.469	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-resp3-itt-a.sas Date: 18:00/13APR2023

Table 35.2.1.3.3.1a
Proportion of Patients with >=16.5 Points Reduction in TSS of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=16.5 Point Reduction in TSS at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Baseline ISM Status						0.149
Moderate	1/ 26 (3.8) (0.1, 19.6)	12/ 52 (23.1) (12.5, 36.8)	6.68 (0.92, 314.09) 0.039	5.26 (0.83, 33.30) 0.078	0.19 (0.05, 0.33) 0.009	
Severe	18/ 45 (40.0) (25.7, 55.7)	42/ 87 (48.3) (37.4, 59.2)	1.39 (0.64, 3.14) 0.356	1.22 (0.78, 1.91) 0.387	0.09 (-0.10, 0.27) 0.361	
Baseline Serum Tryptase (ng/mL)						0.003
< 20	9/ 15 (60.0) (32.3, 83.7)	8/ 28 (28.6) (13.2, 48.7)	0.29 (0.07, 1.37) 0.074	0.51 (0.24, 1.07) >0.999	-0.28 (-0.59, 0.02) 0.067	
>= 20	10/ 56 (17.9) (8.9, 30.4)	46/113 (40.7) (31.6, 50.4)	3.60 (1.45, 8.74) 0.002	2.24 (1.26, 3.99) 0.006	0.23 (0.10, 0.35) <0.001	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-resp3-itt-a.sas Date: 18:00/13APR2023

Table 35.2.1.3.3.1a
Proportion of Patients with >=16.5 Points Reduction in TSS of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >=16.5 Point Reduction in TSS at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.889
0 or 1	18/ 67 (26.9) (16.8, 39.1)	50/131 (38.2) (29.8, 47.1)	1.84 (0.91, 3.93) 0.070	1.48 (0.94, 2.34) 0.090	0.13 (-0.01, 0.26) 0.061	
2+	1/ 4 (25.0) (0.6, 80.6)	4/ 10 (40.0) (12.2, 73.8)	2.07 (0.08, 130.83) 0.625	1.53 (0.29, 8.02) 0.613	0.15 (-0.38, 0.68) 0.584	
Prior TKI therapy						0.711
Yes	1/ 4 (25.0) (0.6, 80.6)	6/ 10 (60.0) (26.2, 87.8)	NE (0.05, NE) 0.317	1.75 (0.40, 7.61) 0.456	0.23 (-0.18, 0.63) 0.277	
No	18/ 67 (26.9) (16.8, 39.1)	48/131 (36.6) (28.4, 45.5)	1.70 (0.84, 3.61) 0.111	1.42 (0.90, 2.26) 0.135	0.11 (-0.02, 0.24) 0.103	

Abbreviations: TSS = Total Symptom Score, ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14 day average of TSS from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of TSS prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient is missing more than 7 days of score 14 day prior to C7D1 visit, the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tss-resp3-itt-a.sas Date: 18:00/13APR2023

Table 35.2.2.2.3.1a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	25/ 71 (35.2) (24.2, 47.5)	45/141 (31.9) (24.3, 40.3)	0.90 (0.45, 1.81) 0.745	0.94 (0.64, 1.38) >0.999	-0.02 (-0.15, 0.11) 0.749	
Age Group (Years)						0.119
< 65	24/ 60 (40.0) (27.6, 53.5)	41/132 (31.1) (23.3, 39.7)	0.74 (0.36, 1.54) 0.382	0.84 (0.57, 1.24) >0.999	-0.06 (-0.20, 0.08) 0.389	
>= 65	1/ 11 (9.1) (0.2, 41.3)	4/ 9 (44.4) (13.7, 78.8)	NE (0.82, NE) 0.044	NE (NE, NE) NE	0.41 (0.06, 0.77) 0.021	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-dom-resp-itt-a.sas Date: 15:07/14APR2023

Table 35.2.2.2.3.1a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Sex						0.646
Male	7/ 17 (41.2) (18.4, 67.1)	13/ 41 (31.7) (18.1, 48.1)	0.68 (0.16, 2.94) 0.545	0.81 (0.41, 1.60) >0.999	-0.08 (-0.34, 0.18) 0.555	
Female	18/ 54 (33.3) (21.1, 47.5)	32/100 (32.0) (23.0, 42.1)	0.98 (0.43, 2.24) 0.958	0.99 (0.62, 1.56) >0.999	-0.00 (-0.15, 0.15) 0.958	
Region						0.342
North America	10/ 33 (30.3) (15.6, 48.7)	20/ 60 (33.3) (21.7, 46.7)	1.30 (0.45, 4.03) 0.587	1.18 (0.64, 2.16) 0.592	0.05 (-0.14, 0.25) 0.586	
Europe	15/ 38 (39.5) (24.0, 56.6)	25/ 81 (30.9) (21.1, 42.1)	0.68 (0.26, 1.74) 0.361	0.80 (0.49, 1.30) >0.999	-0.08 (-0.26, 0.10) 0.373	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-dom-resp-itt-a.sas Date: 15:07/14APR2023

Table 35.2.2.2.3.1a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country						0.974
BEL	1/ 1 (100.0) (2.5, 100.0)	0/ 3 (0.0) (0.0, 70.8)	NE (0.05, NE) 0.317	NE (NE, NE) NE	1.00 (1.00, 1.00) NE	
CAN	0/ 5 (0.0) (0.0, 52.2)	4/ 8 (50.0) (15.7, 84.3)	NE (0.52, NE) 0.059	NE (NE, NE) NE	0.60 (0.20, 1.00) 0.004	
CHE	0/ 1 (0.0) (0.0, 97.5)	0/ 2 (0.0) (0.0, 84.2)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DEU	9/ 15 (60.0) (32.3, 83.7)	6/ 19 (31.6) (12.6, 56.6)	0.22 (0.02, 1.50) 0.071	0.53 (0.26, 1.08) >0.999	-0.28 (-0.57, 0.01) 0.061	
DNK	0/0	1/ 1 (100.0) (2.5, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-dom-resp-itt-a.sas Date: 15:07/14APR2023

Table 35.2.2.2.3.1a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
ESP	0/ 3 (0.0) (0.0, 70.8)	6/ 14 (42.9) (17.7, 71.1)	NE (0.30, NE) 0.123	NE (NE, NE) NE	0.41 (0.10, 0.72) 0.009	
FRA	1/ 6 (16.7) (0.4, 64.1)	4/ 11 (36.4) (10.9, 69.2)	NE (0.17, NE) 0.237	2.50 (0.39, 16.05) 0.334	0.23 (-0.08, 0.55) 0.150	
GBR	2/ 5 (40.0) (5.3, 85.3)	3/ 11 (27.3) (6.0, 61.0)	0.48 (0.03, 10.71) 0.581	0.58 (0.09, 3.91) >0.999	-0.15 (-0.68, 0.37) 0.564	
ITA	0/0	1/ 4 (25.0) (0.6, 80.6)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-dom-resp-itt-a.sas Date: 15:07/14APR2023

Table 35.2.2.2.3.1a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
NLD	0/ 3 (0.0) (0.0, 70.8)	2/ 9 (22.2) (2.8, 60.0)	NE (0.05, NE) 0.317	NE (NE, NE) NE	0.33 (-0.20, 0.87) 0.221	
NOR	1/ 3 (33.3) (0.8, 90.6)	1/ 5 (20.0) (0.5, 71.6)	0.60 (0.01, 45.78) 0.695	0.60 (0.05, 7.92) >0.999	-0.14 (-0.90, 0.62) 0.713	
SWE	1/ 1 (100.0) (2.5, 100.0)	1/ 2 (50.0) (1.3, 98.7)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
USA	10/ 28 (35.7) (18.6, 55.9)	16/ 52 (30.8) (18.7, 45.1)	1.03 (0.32, 3.49) 0.963	1.01 (0.55, 1.86) 0.963	0.00 (-0.20, 0.21) 0.963	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-dom-resp-itt-a.sas Date: 15:07/14APR2023

Table 35.2.2.2.3.1a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Baseline ISM Status						0.092
Moderate	1/ 26 (3.8) (0.1, 19.6)	8/ 52 (15.4) (6.9, 28.1)	3.78 (0.57, 223.34) 0.120	3.78 (0.56, 25.52) 0.172	0.12 (-0.01, 0.26) 0.077	
Severe	24/ 45 (53.3) (37.9, 68.3)	37/ 87 (42.5) (32.0, 53.6)	0.67 (0.30, 1.45) 0.259	0.80 (0.54, 1.18) >0.999	-0.10 (-0.29, 0.08) 0.264	
Baseline Serum Tryptase (ng/mL)						0.002
< 20	10/ 15 (66.7) (38.4, 88.2)	5/ 28 (17.9) (6.1, 36.9)	0.08 (0.01, 0.61) 0.003	0.33 (0.16, 0.72) >0.999	-0.43 (-0.70, -0.15) 0.002	
>= 20	15/ 56 (26.8) (15.8, 40.3)	40/113 (35.4) (26.6, 45.0)	1.55 (0.69, 3.50) 0.260	1.30 (0.82, 2.07) 0.267	0.08 (-0.06, 0.22) 0.241	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-dom-resp-itt-a.sas Date: 15:07/14APR2023

Table 35.2.2.2.3.1a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Gastrointestinal Domain Score Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.689
0 or 1	24/ 67 (35.8) (24.5, 48.5)	41/131 (31.3) (23.5, 40.0)	0.87 (0.42, 1.80) 0.686	0.92 (0.62, 1.37) >0.999	-0.03 (-0.16, 0.11) 0.691	
2+	1/ 4 (25.0) (0.6, 80.6)	4/ 10 (40.0) (12.2, 73.8)	2.07 (0.08, 130.83) 0.625	1.53 (0.29, 8.02) 0.613	0.15 (-0.38, 0.68) 0.584	
Prior TKI therapy						0.610
Yes	1/ 4 (25.0) (0.6, 80.6)	5/ 10 (50.0) (18.7, 81.3)	0.89 (0.01, 84.88) 0.951	0.95 (0.29, 3.13) >0.999	-0.02 (-0.54, 0.51) 0.944	
No	24/ 67 (35.8) (24.5, 48.5)	40/131 (30.5) (22.8, 39.2)	0.86 (0.42, 1.77) 0.651	0.91 (0.61, 1.37) >0.999	-0.03 (-0.17, 0.10) 0.658	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-dom-resp-itt-a.sas Date: 15:07/14APR2023

Table 35.2.2.2.3.1a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Skin Domain Score Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	19/ 71 (26.8) (16.9, 38.6)	72/141 (51.1) (42.5, 59.6)	2.95 (1.53, 5.96) <0.001	1.94 (1.27, 2.96) 0.002	0.25 (0.12, 0.38) <0.001	
Age Group (Years)						0.389
< 65	16/ 60 (26.7) (16.1, 39.7)	65/132 (49.2) (40.4, 58.1)	3.01 (1.44, 6.37) 0.001	1.94 (1.23, 3.06) 0.004	0.24 (0.11, 0.38) <0.001	
>= 65	3/ 11 (27.3) (6.0, 61.0)	7/ 9 (77.8) (40.0, 97.2)	8.22 (0.73, 491.68) 0.042	3.41 (0.78, 14.88) 0.103	0.53 (0.11, 0.95) 0.013	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-dom-resp-itt-a.sas Date: 15:07/14APR2023

Table 35.2.2.2.3.1a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Skin Domain Score Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Sex						0.809
Male	4/ 17 (23.5) (6.8, 49.9)	18/ 41 (43.9) (28.5, 60.3)	2.73 (0.63, 13.24) 0.144	1.86 (0.76, 4.56) 0.173	0.20 (-0.04, 0.45) 0.101	
Female	15/ 54 (27.8) (16.5, 41.6)	54/100 (54.0) (43.7, 64.0)	3.14 (1.48, 7.20) 0.001	2.00 (1.23, 3.26) 0.005	0.27 (0.12, 0.43) <0.001	
Region						0.708
North America	10/ 33 (30.3) (15.6, 48.7)	31/ 60 (51.7) (38.4, 64.8)	2.41 (0.88, 6.67) 0.061	1.67 (0.93, 3.02) 0.086	0.21 (-0.00, 0.41) 0.051	
Europe	9/ 38 (23.7) (11.4, 40.2)	41/ 81 (50.6) (39.3, 61.9)	3.49 (1.35, 9.56) 0.004	2.16 (1.18, 3.97) 0.013	0.27 (0.10, 0.44) 0.002	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-dom-resp-itt-a.sas Date: 15:07/14APR2023

Table 35.2.2.2.3.1a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Skin Domain Score Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country						0.998
BEL	1/ 1 (100.0) (2.5, 100.0)	1/ 3 (33.3) (0.8, 90.6)	0.00 (0.00, 19.00) 0.317	0.00 (NE, NE) NE	-1.00 (-1.00, -1.00) NE	
CAN	0/ 5 (0.0) (0.0, 52.2)	5/ 8 (62.5) (24.5, 91.5)	NE (0.52, NE) 0.059	NE (NE, NE) NE	0.60 (0.20, 1.00) 0.004	
CHE	0/ 1 (0.0) (0.0, 97.5)	2/ 2 (100.0) (15.8, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DEU	4/ 15 (26.7) (7.8, 55.1)	10/ 19 (52.6) (28.9, 75.6)	5.26 (0.68, 55.64) 0.075	2.17 (0.88, 5.36) 0.092	0.29 (0.01, 0.57) 0.040	
DNK	0/0	1/ 1 (100.0) (2.5, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-dom-resp-itt-a.sas Date: 15:07/14APR2023

Table 35.2.2.2.3.1a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Skin Domain Score Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
ESP	1/ 3 (33.3) (0.8, 90.6)	9/ 14 (64.3) (35.1, 87.2)	2.21 (0.10, 293.74) 0.402	1.81 (0.25, 13.21) 0.559	0.26 (-0.44, 0.96) 0.471	
FRA	1/ 6 (16.7) (0.4, 64.1)	6/ 11 (54.5) (23.4, 83.3)	9.50 (0.49, 379.95) 0.095	5.25 (0.47, 59.01) 0.179	0.53 (0.08, 0.98) 0.021	
GBR	0/ 5 (0.0) (0.0, 52.2)	5/ 11 (45.5) (16.7, 76.6)	NE (0.68, NE) 0.070	NE (NE, NE) NE	0.51 (0.18, 0.84) 0.003	
ITA	0/0	0/ 4 (0.0) (0.0, 60.2)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-dom-resp-itt-a.sas Date: 15:07/14APR2023

Table 35.2.2.2.3.1a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Skin Domain Score Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
NLD	1/ 3 (33.3) (0.8, 90.6)	4/ 9 (44.4) (13.7, 78.8)	1.00 (0.01, 117.33) >0.999	1.00 (0.10, 9.61) >0.999	0.00 (-0.75, 0.75) >0.999	
NOR	1/ 3 (33.3) (0.8, 90.6)	1/ 5 (20.0) (0.5, 71.6)	0.60 (0.01, 45.78) 0.695	0.60 (0.05, 7.92) >0.999	-0.14 (-0.90, 0.62) 0.713	
SWE	0/ 1 (0.0) (0.0, 97.5)	2/ 2 (100.0) (15.8, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
USA	10/ 28 (35.7) (18.6, 55.9)	26/ 52 (50.0) (35.8, 64.2)	1.94 (0.67, 5.76) 0.177	1.46 (0.81, 2.62) 0.204	0.16 (-0.07, 0.39) 0.164	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-dom-resp-itt-a.sas Date: 15:07/14APR2023

Table 35.2.2.2.3.1a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Skin Domain Score Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Baseline ISM Status						0.752
Moderate	5/ 26 (19.2) (6.6, 39.4)	20/ 52 (38.5) (25.3, 53.0)	2.58 (0.76, 9.94) 0.097	1.97 (0.84, 4.65) 0.120	0.19 (-0.01, 0.39) 0.068	
Severe	14/ 45 (31.1) (18.2, 46.6)	52/ 87 (59.8) (48.7, 70.1)	3.15 (1.42, 7.48) 0.002	1.93 (1.19, 3.12) 0.008	0.28 (0.11, 0.46) 0.001	
Baseline Serum Tryptase (ng/mL)						0.137
< 20	6/ 15 (40.0) (16.3, 67.7)	12/ 28 (42.9) (24.5, 62.8)	1.18 (0.28, 5.29) 0.803	1.10 (0.51, 2.41) 0.802	0.04 (-0.27, 0.35) 0.797	
>= 20	13/ 56 (23.2) (13.0, 36.4)	60/113 (53.1) (43.5, 62.5)	3.92 (1.81, 9.05) <0.001	2.30 (1.39, 3.80) 0.001	0.30 (0.16, 0.44) <0.0001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-dom-resp-itt-a.sas Date: 15:07/14APR2023

Table 35.2.2.2.3.1a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Skin Domain Score Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.913
0 or 1	18/ 67 (26.9) (16.8, 39.1)	67/131 (51.1) (42.3, 60.0)	2.99 (1.51, 6.16) <0.001	1.95 (1.26, 3.02) 0.003	0.25 (0.12, 0.39) <0.001	
2+	1/ 4 (25.0) (0.6, 80.6)	5/ 10 (50.0) (18.7, 81.3)	3.60 (0.12, 222.17) 0.417	1.87 (0.39, 9.01) 0.437	0.24 (-0.27, 0.75) 0.354	
Prior TKI therapy						0.669
Yes	1/ 4 (25.0) (0.6, 80.6)	7/ 10 (70.0) (34.8, 93.3)	3.88 (0.20, 222.87) 0.245	3.88 (0.14, 104.07) 0.420	0.43 (-0.25, 1.00) 0.211	
No	18/ 67 (26.9) (16.8, 39.1)	65/131 (49.6) (40.8, 58.5)	2.81 (1.43, 5.84) 0.001	1.90 (1.23, 2.95) 0.004	0.24 (0.10, 0.37) <0.001	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-dom-resp-itt-a.sas Date: 15:07/14APR2023

Table 35.2.2.2.3.1a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	20/ 71 (28.2) (18.1, 40.1)	49/141 (34.8) (26.9, 43.2)	1.43 (0.72, 2.87) 0.284	1.26 (0.82, 1.93) 0.294	0.07 (-0.06, 0.20) 0.269	
Age Group (Years)						0.401
< 65	19/ 60 (31.7) (20.3, 45.0)	46/132 (34.8) (26.8, 43.6)	1.29 (0.63, 2.69) 0.466	1.17 (0.76, 1.81) 0.473	0.05 (-0.09, 0.19) 0.454	
>= 65	1/ 11 (9.1) (0.2, 41.3)	3/ 9 (33.3) (7.5, 70.1)	6.33 (0.24, 321.69) 0.222	4.56 (0.31, 66.20) 0.267	0.26 (-0.11, 0.63) 0.166	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-dom-resp-itt-a.sas Date: 15:07/14APR2023

Table 35.2.2.2.3.1a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Sex						0.071
Male	6/ 17 (35.3) (14.2, 61.7)	9/ 41 (22.0) (10.6, 37.6)	0.46 (0.09, 2.36) 0.287	0.64 (0.29, 1.39) >0.999	-0.13 (-0.36, 0.11) 0.296	
Female	14/ 54 (25.9) (15.0, 39.7)	40/100 (40.0) (30.3, 50.3)	2.04 (0.91, 4.59) 0.062	1.59 (0.95, 2.64) 0.075	0.15 (0.00, 0.30) 0.048	
Region						0.399
North America	10/ 33 (30.3) (15.6, 48.7)	18/ 60 (30.0) (18.8, 43.2)	0.98 (0.34, 2.91) 0.966	0.99 (0.51, 1.92) >0.999	-0.00 (-0.20, 0.19) 0.965	
Europe	10/ 38 (26.3) (13.4, 43.1)	31/ 81 (38.3) (27.7, 49.7)	1.89 (0.72, 5.11) 0.164	1.48 (0.83, 2.63) 0.183	0.13 (-0.04, 0.29) 0.141	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-dom-resp-itt-a.sas Date: 15:07/14APR2023

Table 35.2.2.2.3.1a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster

Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country						0.999
BEL	0/ 1 (0.0) (0.0, 97.5)	0/ 3 (0.0) (0.0, 70.8)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
CAN	1/ 5 (20.0) (0.5, 71.6)	4/ 8 (50.0) (15.7, 84.3)	2.17 (0.11, 176.61) 0.473	2.17 (0.23, 20.60) 0.501	0.28 (-0.49, 1.00) 0.474	
CHE	0/ 1 (0.0) (0.0, 97.5)	1/ 2 (50.0) (1.3, 98.7)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DEU	5/ 15 (33.3) (11.8, 61.6)	6/ 19 (31.6) (12.6, 56.6)	0.97 (0.16, 6.18) 0.970	0.98 (0.38, 2.51) >0.999	-0.01 (-0.30, 0.29) 0.968	
DNK	0/0	1/ 1 (100.0) (2.5, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-dom-resp-itt-a.sas Date: 15:07/14APR2023

Table 35.2.2.2.3.1a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
ESP	1/ 3 (33.3) (0.8, 90.6)	6/ 14 (42.9) (17.7, 71.1)	1.64 (0.07, 111.31) 0.689	1.43 (0.20, 10.13) 0.721	0.14 (-0.52, 0.79) 0.682	
FRA	0/ 6 (0.0) (0.0, 45.9)	5/ 11 (45.5) (16.7, 76.6)	NE (0.63, NE) 0.069	NE (NE, NE) NE	0.47 (0.08, 0.85) 0.017	
GBR	1/ 5 (20.0) (0.5, 71.6)	4/ 11 (36.4) (10.9, 69.2)	2.60 (0.12, 166.69) 0.528	1.96 (0.25, 15.62) 0.525	0.18 (-0.29, 0.64) 0.457	
ITA	0/0	1/ 4 (25.0) (0.6, 80.6)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-dom-resp-itt-a.sas Date: 15:07/14APR2023

Table 35.2.2.2.3.1a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
NLD	1/ 3 (33.3) (0.8, 90.6)	3/ 9 (33.3) (7.5, 70.1)	1.00 (0.01, 117.33) >0.999	1.00 (0.10, 9.61) >0.999	0.00 (-0.75, 0.75) >0.999	
NOR	1/ 3 (33.3) (0.8, 90.6)	3/ 5 (60.0) (14.7, 94.7)	NE (0.04, NE) 0.414	1.60 (0.51, 5.00) 0.418	0.21 (-0.21, 0.64) 0.323	
SWE	1/ 1 (100.0) (2.5, 100.0)	1/ 2 (50.0) (1.3, 98.7)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
USA	9/ 28 (32.1) (15.9, 52.4)	14/ 52 (26.9) (15.6, 41.0)	0.84 (0.27, 2.75) 0.750	0.89 (0.44, 1.79) >0.999	-0.03 (-0.24, 0.17) 0.747	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-dom-resp-itt-a.sas Date: 15:07/14APR2023

Table 35.2.2.2.3.1a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Baseline ISM Status						0.582
Moderate	3/ 26 (11.5) (2.4, 30.2)	11/ 52 (21.2) (11.1, 34.7)	1.97 (0.45, 11.96) 0.332	1.76 (0.55, 5.65) 0.343	0.09 (-0.08, 0.26) 0.289	
Severe	17/ 45 (37.8) (23.8, 53.5)	38/ 87 (43.7) (33.1, 54.7)	1.29 (0.58, 2.89) 0.502	1.16 (0.74, 1.84) 0.512	0.06 (-0.12, 0.24) 0.496	
Baseline Serum Tryptase (ng/mL)						0.162
< 20	7/ 15 (46.7) (21.3, 73.4)	9/ 28 (32.1) (15.9, 52.4)	0.60 (0.14, 2.77) 0.461	0.74 (0.34, 1.60) >0.999	-0.12 (-0.42, 0.19) 0.455	
>= 20	13/ 56 (23.2) (13.0, 36.4)	40/113 (35.4) (26.6, 45.0)	1.87 (0.83, 4.32) 0.104	1.51 (0.90, 2.54) 0.119	0.12 (-0.02, 0.26) 0.086	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-dom-resp-itt-a.sas Date: 15:07/14APR2023

Table 35.2.2.2.3.1a
Proportion of Patients with >=4.5 Points Reduction in Domain Score of ISM-SAF at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Neurocognitive Symptom Cluster Patients with >= 4.5 Point Reduction at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.505
0 or 1	19/ 67 (28.4) (18.0, 40.7)	47/131 (35.9) (27.7, 44.7)	1.52 (0.75, 3.14) 0.217	1.31 (0.84, 2.03) 0.231	0.09 (-0.05, 0.22) 0.202	
2+	1/ 4 (25.0) (0.6, 80.6)	2/ 10 (20.0) (2.5, 55.6)	0.84 (0.03, 57.61) 0.894	0.87 (0.12, 6.18) >0.999	-0.04 (-0.59, 0.52) 0.896	
Prior TKI therapy						0.771
Yes	1/ 4 (25.0) (0.6, 80.6)	5/ 10 (50.0) (18.7, 81.3)	NE (0.03, NE) 0.439	1.56 (0.41, 6.01) 0.516	0.17 (-0.19, 0.53) 0.351	
No	19/ 67 (28.4) (18.0, 40.7)	44/131 (33.6) (25.6, 42.4)	1.36 (0.67, 2.80) 0.366	1.22 (0.78, 1.92) 0.375	0.06 (-0.07, 0.20) 0.354	

Abbreviations: ISM-SAF = Indolent Systemic Mastocytosis-Symptom Assessment Form, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.

Note: Baseline score is defined as the 14-day average of domain score from C1D-14 to C1D-1. C7D1 score is defined as the 14-day average of domain score prior to C7D1 visit. If a patient is missing more than 7 days of score between C1D-14 and C1D-1, the baseline score is considered as missing for the patient. If a patient misses more than 7 days of the score from the 14 days period for calculating C7D1 score, then the C7D1 score is considered as missing for the patient. Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 score will be counted in the denominator.

Patients with high-dose steroid use within 7 days before C7D1, or greater than 14 consecutive days at any point from C1D1 to C7D1, will be counted in the denominator but not numerator.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ismsaf-dom-resp-itt-a.sas Date: 15:07/14APR2023

Table 35.2.3.2.1.2a
Change from Baseline in Serum Tryptase (ng/mL) by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	17	41	54	100	
Mean (StdDev)	89.82 (118.767)	62.43 (60.363)	60.56 (53.046)	55.57 (51.909)	
Median	47.00	36.50	43.60	38.80	
Min, Max	7.4, 501.6	4.2, 248.8	5.7, 235.2	3.6, 256.0	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-sex-a.sas Date: 15:40/07AUG2023

Table 35.2.3.2.1.2a
Change from Baseline in Serum Tryptase (ng/mL) by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	15	40	51	93	
Mean (StdDev)	106.51 (147.305)	31.69 (35.081)	57.73 (51.029)	29.78 (34.496)	
Median	67.30	18.65	38.10	18.00	
Min, Max	7.5, 592.8	3.0, 153.0	4.9, 236.0	2.2, 196.0	
C2D1 CFB					
n	15	40	51	93	
LS Mean (StdErr) [2]	14.51 (7.686)	-26.09 (5.051)	5.40 (3.962)	-20.27 (3.265)	
95% CI [2]	-0.92, 29.94	-36.23, -15.95	-2.43, 13.23	-26.72, -13.81	
Difference (95% CI) in CFB [2]		-40.60 (-58.04, -23.17)		-25.67 (-34.47, -16.87)	
p-value [3]		<0.0001		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-sex-a.sas Date: 15:40/07AUG2023

Table 35.2.3.2.1.2a
Change from Baseline in Serum Tryptase (ng/mL) by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	40	45	96	
Mean (StdDev)	94.95 (128.183)	30.28 (37.405)	60.62 (56.705)	26.68 (31.626)	
Median	40.20	14.30	38.10	18.10	
Min, Max	6.2, 536.8	2.6, 172.0	5.2, 276.0	2.0, 154.0	
C3D1 CFB					
n	17	40	45	96	
LS Mean (StdErr) [2]	11.51 (6.854)	-26.98 (4.722)	8.66 (4.419)	-21.73 (3.403)	
95% CI [2]	-2.24, 25.26	-36.45, -17.51	-0.08, 17.40	-28.46, -15.00	
Difference (95% CI) in CFB [2]		-38.49 (-54.07, -22.91)		-30.38 (-40.03, -20.74)	
p-value [3]		<0.0001		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-sex-a.sas Date: 15:40/07AUG2023

Table 35.2.3.2.1.2a
Change from Baseline in Serum Tryptase (ng/mL) by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	14	38	47	94	
Mean (StdDev)	104.24 (141.283)	31.33 (39.103)	59.02 (58.322)	27.16 (34.363)	
Median	47.95	14.20	38.20	15.75	
Min, Max	7.3, 540.0	2.5, 148.0	5.2, 256.0	3.3, 162.0	
C4D1 CFB					
n	14	38	47	94	
LS Mean (StdErr) [2]	11.06 (6.638)	-24.00 (4.400)	8.18 (4.075)	-20.99 (3.224)	
95% CI [2]	-2.29, 24.41	-32.85, -15.16	0.12, 16.24	-27.36, -14.61	
Difference (95% CI) in CFB [2]		-35.07 (-50.24, -19.89)		-29.17 (-38.02, -20.32)	
p-value [3]		<0.0001		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-sex-a.sas Date: 15:40/07AUG2023

Table 35.2.3.2.1.2a
Change from Baseline in Serum Tryptase (ng/mL) by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	15	39	45	94	
Mean (StdDev)	96.27 (141.059)	35.47 (49.072)	61.06 (64.531)	24.91 (30.301)	
Median	42.70	13.90	35.00	15.40	
Min, Max	6.8, 565.6	3.1, 184.8	5.4, 280.8	2.3, 167.0	
C5D1 CFB					
n	15	39	45	94	
LS Mean (StdErr) [2]	10.10 (7.950)	-23.53 (5.269)	10.40 (4.683)	-19.89 (3.646)	
95% CI [2]	-5.87, 26.06	-34.11, -12.94	1.14, 19.66	-27.10, -12.68	
Difference (95% CI) in CFB [2]		-33.62 (-51.75, -15.50)		-30.29 (-40.59, -19.99)	
p-value [3]		<0.001		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-sex-a.sas Date: 15:40/07AUG2023

Table 35.2.3.2.1.2a
Change from Baseline in Serum Tryptase (ng/mL) by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	16	39	46	89	
Mean (StdDev)	95.78 (135.736)	36.70 (52.287)	65.21 (67.008)	25.84 (30.018)	
Median	37.40	11.80	36.95	15.60	
Min, Max	6.9, 554.4	3.0, 183.2	5.3, 325.6	2.0, 143.0	
C6D1 CFB					
n	16	39	46	89	
LS Mean (StdErr) [2]	10.60 (8.182)	-21.82 (5.658)	10.01 (4.841)	-21.53 (3.853)	
95% CI [2]	-5.82, 27.03	-33.18, -10.46	0.44, 19.59	-29.15, -13.90	
Difference (95% CI) in CFB [2]		-32.42 (-51.02, -13.82)		-31.54 (-42.31, -20.77)	
p-value [3]		<0.001		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-sex-a.sas Date: 15:40/07AUG2023

Table 35.2.3.2.1.2a
Change from Baseline in Serum Tryptase (ng/mL) by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	17	40	47	94	
Mean (StdDev)	98.92 (141.147)	39.59 (58.813)	66.74 (80.908)	27.77 (34.869)	
Median	39.90	12.85	38.80	14.55	
Min, Max	6.5, 590.4	3.2, 234.4	5.5, 444.0	2.1, 195.0	
C7D1 CFB					
n	17	40	47	94	
LS Mean (StdErr) [2]	12.83 (8.610)	-20.43 (5.931)	14.46 (6.380)	-22.48 (5.078)	
95% CI [2]	-4.44, 30.10	-32.33, -8.54	1.85, 27.08	-32.52, -12.44	
Difference (95% CI) in CFB [2]		-33.26 (-52.83, -13.70)		-36.94 (-50.86, -23.02)	
Hedges'G (95% CI) in CFB		-0.89 (-1.53, -0.32)		-0.77 (-1.15, -0.42)	
p-value [3]		0.001		<0.0001	
					0.761

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-sex-a.sas Date: 15:40/07AUG2023

Table 35.2.3.2.1.3a
Change from Baseline in Serum Tryptase (ng/mL) by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	33	60	38	81	
Mean (StdDev)	51.75 (41.414)	58.99 (55.990)	81.30 (92.355)	56.51 (53.468)	
Median	43.70	38.50	45.80	37.40	
Min, Max	5.7, 159.0	3.6, 256.0	5.7, 501.6	4.2, 248.8	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-reg-a.sas Date: 15:40/07AUG2023

Table 35.2.3.2.1.3a
Change from Baseline in Serum Tryptase (ng/mL) by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	28	57	38	76	
Mean (StdDev)	48.55 (40.258)	27.90 (29.523)	83.75 (103.691)	32.20 (37.977)	
Median	37.50	18.00	47.40	18.65	
Min, Max	4.9, 157.0	2.2, 165.0	5.6, 592.8	3.4, 196.0	
C2D1 CFB					
n	28	57	38	76	
LS Mean (StdErr) [2]	7.34 (6.224)	-25.09 (4.875)	6.96 (4.007)	-20.51 (3.042)	
95% CI [2]	-5.05, 19.72	-34.79, -15.38	-0.98, 14.90	-26.54, -14.48	
Difference (95% CI) in CFB [2]		-32.42 (-46.71, -18.14)		-27.47 (-36.32, -18.61)	
p-value [3]		<0.0001		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-reg-a.sas Date: 15:40/07AUG2023

Table 35.2.3.2.1.3a
Change from Baseline in Serum Tryptase (ng/mL) by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	26	58	36	78	
Mean (StdDev)	53.03 (44.246)	26.84 (30.740)	82.32 (100.998)	28.41 (35.311)	
Median	39.15	16.75	37.85	17.15	
Min, Max	5.2, 174.0	2.0, 151.0	5.8, 536.8	3.1, 172.0	
C3D1 CFB					
n	26	58	36	78	
LS Mean (StdErr) [2]	9.50 (6.774)	-25.76 (5.076)	8.65 (4.040)	-22.21 (2.958)	
95% CI [2]	-3.99, 22.98	-35.87, -15.66	0.64, 16.66	-28.07, -16.34	
Difference (95% CI) in CFB [2]		-35.26 (-50.47, -20.04)		-30.85 (-39.75, -21.96)	
p-value [3]		<0.0001		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-reg-a.sas Date: 15:40/07AUG2023

Table 35.2.3.2.1.3a
Change from Baseline in Serum Tryptase (ng/mL) by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	24	55	37	77	
Mean (StdDev)	48.18 (49.804)	29.14 (36.175)	83.16 (100.436)	27.80 (35.566)	
Median	36.75	16.10	41.60	15.10	
Min, Max	5.2, 236.0	2.5, 162.0	5.4, 540.0	3.3, 157.0	
C4D1 CFB					
n	24	55	37	77	
LS Mean (StdErr) [2]	7.96 (6.674)	-23.63 (5.107)	8.98 (3.603)	-21.36 (2.658)	
95% CI [2]	-5.34, 21.26	-33.80, -13.45	1.84, 16.12	-26.63, -16.09	
Difference (95% CI) in CFB [2]		-31.59 (-46.56, -16.62)		-30.34 (-38.28, -22.40)	
p-value [3]		<0.0001		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-reg-a.sas Date: 15:40/07AUG2023

Table 35.2.3.2.1.3a
Change from Baseline in Serum Tryptase (ng/mL) by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	25	55	35	78	
Mean (StdDev)	51.26 (57.634)	25.98 (31.424)	83.16 (105.883)	29.44 (40.493)	
Median	32.20	14.90	35.90	15.45	
Min, Max	5.4, 280.8	2.3, 167.0	6.1, 565.6	3.0, 184.8	
C5D1 CFB					
n	25	55	35	78	
LS Mean (StdErr) [2]	10.12 (7.553)	-22.80 (5.645)	10.39 (4.304)	-19.87 (3.142)	
95% CI [2]	-4.93, 25.17	-34.05, -11.56	1.86, 18.92	-26.09, -13.64	
Difference (95% CI) in CFB [2]		-32.92 (-50.06, -15.79)		-30.25 (-39.75, -20.75)	
p-value [3]		<0.001		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-reg-a.sas Date: 15:40/07AUG2023

Table 35.2.3.2.1.3a
Change from Baseline in Serum Tryptase (ng/mL) by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	28	51	34	77	
Mean (StdDev)	59.25 (67.997)	28.57 (33.893)	84.50 (103.700)	29.53 (41.187)	
Median	36.95	14.50	38.50	14.50	
Min, Max	6.4, 325.6	2.0, 139.0	5.3, 554.4	2.8, 183.2	
C6D1 CFB					
n	28	51	34	77	
LS Mean (StdErr) [2]	13.27 (7.194)	-23.49 (5.797)	7.91 (4.887)	-19.86 (3.559)	
95% CI [2]	-1.07, 27.60	-35.05, -11.94	-1.78, 17.60	-26.92, -12.80	
Difference (95% CI) in CFB [2]		-36.76 (-53.21, -20.31)		-27.77 (-38.60, -16.94)	
p-value [3]		<0.0001		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-reg-a.sas Date: 15:40/07AUG2023

Table 35.2.3.2.1.3a
Change from Baseline in Serum Tryptase (ng/mL) by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	28	57	36	77	
Mean (StdDev)	60.04 (82.471)	31.06 (39.842)	87.14 (111.815)	31.47 (46.310)	
Median	38.30	14.40	40.40	13.80	
Min, Max	5.9, 444.0	2.1, 195.0	5.5, 590.4	3.5, 234.4	
C7D1 CFB					
n	28	57	36	77	
LS Mean (StdErr) [2]	16.60 (9.712)	-25.47 (7.681)	12.41 (5.258)	-18.89 (3.830)	
95% CI [2]	-2.73, 35.93	-40.76, -10.19	1.99, 22.83	-26.49, -11.30	
Difference (95% CI) in CFB [2]		-42.08 (-63.93, -20.22)		-31.31 (-42.86, -19.75)	
Hedges'G (95% CI) in CFB		-0.75 (-1.24, -0.29)		-0.94 (-1.38, -0.54)	
p-value [3]		<0.001		<0.0001	
					0.352

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-reg-a.sas Date: 15:40/07AUG2023

Table 35.2.3.2.1.4a
Change from Baseline in Serum Tryptase (ng/mL) by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-cou-a.sas Date: 15:40/07AUG2023

Table 35.2.3.2.1.4a
Change from Baseline in Serum Tryptase (ng/mL) by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-cou-a.sas Date: 15:40/07AUG2023

Table 35.2.3.2.1.4a
Change from Baseline in Serum Tryptase (ng/mL) by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-cou-a.sas Date: 15:40/07AUG2023

Table 35.2.3.2.1.4a
Change from Baseline in Serum Tryptase (ng/mL) by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-cou-a.sas Date: 15:40/07AUG2023

Table 35.2.3.2.1.4a
Change from Baseline in Serum Tryptase (ng/mL) by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-cou-a.sas Date: 15:40/07AUG2023

Table 35.2.3.2.1.5a
Change from Baseline in Serum Tryptase (ng/mL) by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	26	52	45	87	
Mean (StdDev)	79.27 (104.524)	56.73 (54.202)	60.81 (49.346)	57.86 (55.367)	
Median	44.15	34.75	43.50	38.40	
Min, Max	6.1, 501.6	3.6, 248.8	5.7, 159.0	5.5, 256.0	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-ism-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.1.5a
Change from Baseline in Serum Tryptase (ng/mL) by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	24	50	42	81	
Mean (StdDev)	85.30 (122.984)	32.61 (41.796)	59.40 (50.226)	28.96 (29.908)	
Median	42.40	18.20	36.10	18.00	
Min, Max	7.0, 592.8	2.2, 196.0	4.9, 157.0	3.8, 165.0	
C2D1 CFB					
n	24	50	42	81	
LS Mean (StdErr) [2]	8.54 (4.935)	-19.68 (3.499)	5.88 (4.693)	-24.64 (3.776)	
95% CI [2]	-1.30, 18.38	-26.66, -12.71	-3.41, 15.18	-32.11, -17.16	
Difference (95% CI) in CFB [2]		-28.22 (-39.12, -17.32)		-30.52 (-41.40, -19.64)	
p-value [3]		<0.0001		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-ism-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.1.5a
Change from Baseline in Serum Tryptase (ng/mL) by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	52	40	82	
Mean (StdDev)	82.00 (119.411)	29.55 (40.325)	63.46 (54.206)	26.52 (28.698)	
Median	38.60	14.90	38.40	18.10	
Min, Max	6.2, 536.8	2.0, 172.0	5.2, 174.0	3.4, 151.0	
C3D1 CFB					
n	22	52	40	82	
LS Mean (StdErr) [2]	9.09 (4.763)	-21.42 (3.256)	8.97 (5.023)	-25.15 (3.881)	
95% CI [2]	-0.41, 18.59	-27.92, -14.93	-0.97, 18.92	-32.83, -17.46	
Difference (95% CI) in CFB [2]		-30.51 (-40.96, -20.06)		-34.12 (-45.59, -22.65)	
p-value [3]		<0.0001		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-ism-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.1.5a
Change from Baseline in Serum Tryptase (ng/mL) by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	20	50	41	80	
Mean (StdDev)	81.84 (125.523)	30.95 (42.165)	63.33 (57.889)	26.42 (31.566)	
Median	38.00	14.20	39.70	15.10	
Min, Max	6.2, 540.0	2.5, 157.0	5.2, 236.0	4.4, 162.0	
C4D1 CFB					
n	20	50	41	80	
LS Mean (StdErr) [2]	9.55 (5.639)	-21.83 (3.920)	8.52 (4.202)	-22.06 (3.289)	
95% CI [2]	-1.70, 20.81	-29.66, -14.01	0.19, 16.84	-28.58, -15.55	
Difference (95% CI) in CFB [2]		-31.39 (-43.75, -19.02)		-30.58 (-40.21, -20.95)	
p-value [3]		<0.0001		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-ism-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.1.5a
Change from Baseline in Serum Tryptase (ng/mL) by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	22	51	38	80	
Mean (StdDev)	79.86 (124.822)	33.17 (50.146)	64.08 (62.619)	24.53 (25.585)	
Median	33.60	13.30	39.30	15.20	
Min, Max	6.6, 565.6	2.3, 184.8	5.4, 280.8	4.0, 110.0	
C5D1 CFB					
n	22	51	38	80	
LS Mean (StdErr) [2]	8.62 (5.548)	-17.70 (3.807)	10.57 (5.339)	-23.81 (4.077)	
95% CI [2]	-2.44, 19.69	-25.29, -10.11	-0.01, 21.14	-31.88, -15.73	
Difference (95% CI) in CFB [2]		-26.32 (-38.54, -14.11)		-34.37 (-46.62, -22.13)	
p-value [3]		<0.0001		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-ism-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.1.5a
Change from Baseline in Serum Tryptase (ng/mL) by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	47	39	79	
Mean (StdDev)	73.94 (115.074)	34.30 (50.474)	72.60 (72.212)	25.84 (29.270)	
Median	36.20	13.30	45.10	14.50	
Min, Max	6.5, 554.4	2.0, 183.2	5.3, 325.6	4.2, 126.0	
C6D1 CFB					
n	23	47	39	79	
LS Mean (StdErr) [2]	5.55 (5.493)	-18.24 (3.960)	13.32 (5.564)	-23.27 (4.296)	
95% CI [2]	-5.42, 16.51	-26.14, -10.34	2.29, 24.34	-31.78, -14.76	
Difference (95% CI) in CFB [2]		-23.79 (-35.98, -11.59)		-36.58 (-49.37, -23.80)	
p-value [3]		<0.001		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-ism-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.1.5a
Change from Baseline in Serum Tryptase (ng/mL) by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	23	51	41	81	
Mean (StdDev)	83.49 (128.434)	34.56 (54.843)	70.68 (81.776)	28.44 (34.818)	
Median	39.40	13.00	38.50	14.40	
Min, Max	7.1, 590.4	2.1, 234.4	5.5, 444.0	4.4, 195.0	
C7D1 CFB					
n	23	51	41	81	
LS Mean (StdErr) [2]	11.09 (6.457)	-18.09 (4.582)	15.61 (6.991)	-24.22 (5.459)	
95% CI [2]	-1.78, 23.97	-27.22, -8.95	1.77, 29.45	-35.03, -13.41	
Difference (95% CI) in CFB [2]		-29.18 (-43.32, -15.04)		-39.83 (-55.82, -23.83)	
Hedges'G (95% CI) in CFB		-0.90 (-1.45, -0.40)		-0.83 (-1.24, -0.45)	
p-value [3]		<0.001		<0.0001	
					0.368

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-ism-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.1.7a
Change from Baseline in Serum Tryptase (ng/mL) by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	67	131	4	10	
Mean (StdDev)	69.10 (76.001)	55.13 (52.610)	41.80 (24.864)	89.50 (69.189)	
Median	43.70	37.40	36.95	70.35	
Min, Max	5.7, 501.6	3.6, 256.0	21.2, 72.1	6.7, 239.2	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-ecog-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.1.7a
Change from Baseline in Serum Tryptase (ng/mL) by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	62	125	4	8	
Mean (StdDev)	70.64 (86.524)	28.35 (31.717)	40.58 (22.250)	61.75 (59.096)	
Median	39.70	17.70	39.10	47.75	
Min, Max	4.9, 592.8	2.2, 165.0	19.2, 64.9	4.8, 196.0	
C2D1 CFB					
n	62	125	4	8	
LS Mean (StdErr) [2]	6.87 (3.405)	-22.17 (2.613)	24.31 (34.586)	-9.69 (27.269)	
95% CI [2]	0.15, 13.59	-27.33, -17.02	-55.45, 104.07	-72.57, 53.19	
Difference (95% CI) in CFB [2]		-29.04 (-36.71, -21.37)		-34.00 (-103.38, 35.38)	
p-value [3]		<0.0001		0.291	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-ecog-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.1.7a
Change from Baseline in Serum Tryptase (ng/mL) by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	58	127	4	9	
Mean (StdDev)	72.20 (85.175)	26.14 (31.967)	38.68 (19.922)	50.34 (45.099)	
Median	38.60	15.30	33.50	46.80	
Min, Max	5.2, 536.8	2.0, 172.0	21.5, 66.2	7.2, 154.0	
C3D1 CFB					
n	58	127	4	9	
LS Mean (StdErr) [2]	8.95 (3.571)	-22.96 (2.631)	25.42 (33.785)	-20.14 (25.730)	
95% CI [2]	1.90, 15.99	-28.15, -17.77	-51.01, 101.85	-78.35, 38.06	
Difference (95% CI) in CFB [2]		-31.91 (-39.86, -23.95)		-45.56 (-109.51, 18.38)	
p-value [3]		<0.0001		0.141	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-ecog-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.1.7a
Change from Baseline in Serum Tryptase (ng/mL) by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	57	124	4	8	
Mean (StdDev)	71.43 (87.945)	26.87 (34.242)	40.48 (20.895)	51.51 (50.823)	
Median	38.20	15.05	35.30	36.65	
Min, Max	5.2, 540.0	2.5, 162.0	22.8, 68.5	6.7, 157.0	
C4D1 CFB					
n	57	124	4	8	
LS Mean (StdErr) [2]	8.76 (3.604)	-22.36 (2.685)	12.58 (9.286)	-15.89 (7.019)	
95% CI [2]	1.65, 15.88	-27.66, -17.06	-8.83, 33.99	-32.08, 0.29	
Difference (95% CI) in CFB [2]		-31.12 (-39.12, -23.13)		-28.47 (-46.57, -10.38)	
p-value [3]		<0.0001		0.007	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-ecog-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.1.7a
Change from Baseline in Serum Tryptase (ng/mL) by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	56	124	4	9	
Mean (StdDev)	71.85 (92.513)	26.53 (35.387)	42.08 (23.837)	48.33 (52.383)	
Median	35.45	14.70	35.05	36.60	
Min, Max	5.4, 565.6	2.3, 184.8	23.4, 74.8	5.5, 165.6	
C5D1 CFB					
n	56	124	4	9	
LS Mean (StdErr) [2]	10.42 (4.196)	-21.28 (3.076)	13.45 (11.968)	-14.24 (9.114)	
95% CI [2]	2.14, 18.70	-27.36, -15.21	-13.62, 40.53	-34.86, 6.38	
Difference (95% CI) in CFB [2]		-31.71 (-41.10, -22.31)		-27.69 (-50.34, -5.04)	
p-value [3]		<0.0001		0.022	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-ecog-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.1.7a
Change from Baseline in Serum Tryptase (ng/mL) by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	9	
Mean (StdDev)	75.34 (92.134)	27.39 (37.315)	40.60 (19.408)	52.36 (45.915)	
Median	36.95	14.20	36.10	35.00	
Min, Max	5.3, 554.4	2.0, 183.2	24.4, 65.8	4.8, 143.0	
C6D1 CFB					
n	58	119	4	9	
LS Mean (StdErr) [2]	10.12 (4.040)	-20.82 (3.056)	22.01 (35.886)	-18.39 (28.436)	
95% CI [2]	2.14, 18.09	-26.86, -14.79	-59.17, 103.19	-82.71, 45.94	
Difference (95% CI) in CFB [2]		-30.94 (-40.03, -21.86)		-40.40 (-110.43, 29.63)	
p-value [3]		<0.0001		0.224	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-ecog-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.1.7a
Change from Baseline in Serum Tryptase (ng/mL) by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	61	124	3	10	
Mean (StdDev)	76.81 (102.366)	29.96 (43.295)	44.30 (23.036)	47.90 (45.162)	
Median	38.80	13.55	42.00	35.30	
Min, Max	5.5, 590.4	2.1, 234.4	22.5, 68.4	5.4, 142.0	
C7D1 CFB					
n	61	124	3	10	
LS Mean (StdErr) [2]	14.33 (5.083)	-20.95 (3.866)	20.51 (41.927)	-21.20 (29.329)	
95% CI [2]	4.30, 24.36	-28.58, -13.32	-74.33, 115.35	-87.55, 45.15	
Difference (95% CI) in CFB [2]		-35.28 (-46.64, -23.92)		-41.71 (-119.97, 36.55)	
Hedges'G (95% CI) in CFB		-0.84 (-1.17, -0.53)		-0.43 (-2.00, 0.93)	
p-value [3]		<0.0001		0.259	
					0.893

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-ecog-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.1.8a
Change from Baseline in Serum Tryptase (ng/mL) by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	67	131	
Mean (StdDev)	55.58 (49.319)	48.15 (31.371)	68.28 (75.677)	58.29 (55.751)	
Median	46.80	45.60	43.70	37.60	
Min, Max	5.7, 123.0	10.4, 111.0	5.7, 501.6	3.6, 256.0	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-thpy-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.1.8a
Change from Baseline in Serum Tryptase (ng/mL) by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	9	62	124	
Mean (StdDev)	56.13 (53.196)	23.37 (17.368)	69.64 (86.117)	30.87 (35.464)	
Median	44.80	20.80	39.70	18.30	
Min, Max	4.9, 130.0	5.7, 51.0	5.6, 592.8	2.2, 196.0	
C2D1 CFB					
n	4	9	62	124	
LS Mean (StdErr) [2]	3.53 (8.311)	-28.19 (8.311)	7.65 (3.712)	-22.44 (2.851)	
95% CI [2]	-15.27, 22.33	-46.99, -9.39	0.32, 14.97	-28.07, -16.81	
Difference (95% CI) in CFB [2]		-31.72 (-55.69, -7.75)		-30.09 (-38.39, -21.79)	
p-value [3]		0.015		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-thpy-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.1.8a
Change from Baseline in Serum Tryptase (ng/mL) by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	58	126	
Mean (StdDev)	59.15 (57.947)	22.15 (14.400)	70.79 (84.639)	28.18 (34.380)	
Median	45.20	20.10	37.90	16.40	
Min, Max	5.2, 141.0	5.7, 44.2	5.8, 536.8	2.0, 172.0	
C3D1 CFB					
n	4	10	58	126	
LS Mean (StdErr) [2]	5.51 (9.921)	-35.38 (9.921)	9.57 (3.871)	-23.61 (2.850)	
95% CI [2]	-16.59, 27.62	-57.49, -13.28	1.93, 17.21	-29.23, -17.98	
Difference (95% CI) in CFB [2]		-40.90 (-69.01, -12.78)		-33.18 (-41.74, -24.62)	
p-value [3]		0.009		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-thpy-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.1.8a
Change from Baseline in Serum Tryptase (ng/mL) by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	4	9	57	123	
Mean (StdDev)	55.50 (48.822)	20.24 (13.504)	70.38 (87.631)	28.96 (36.750)	
Median	47.40	20.90	37.80	15.10	
Min, Max	5.2, 122.0	6.1, 46.0	5.4, 540.0	2.5, 162.0	
C4D1 CFB					
n	4	9	57	123	
LS Mean (StdErr) [2]	3.86 (10.366)	-31.16 (10.366)	9.04 (3.602)	-22.03 (2.683)	
95% CI [2]	-19.59, 27.31	-54.61, -7.71	1.93, 16.15	-27.33, -16.74	
Difference (95% CI) in CFB [2]		-35.03 (-64.93, -5.13)		-31.08 (-39.02, -23.14)	
p-value [3]		0.026		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-thpy-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.1.8a
Change from Baseline in Serum Tryptase (ng/mL) by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	56	125	
Mean (StdDev)	55.38 (54.745)	23.33 (14.719)	70.90 (92.033)	28.31 (37.916)	
Median	41.55	25.10	34.05	14.90	
Min, Max	5.4, 133.0	6.9, 49.2	6.1, 565.6	2.3, 184.8	
C5D1 CFB					
n	4	8	56	125	
LS Mean (StdErr) [2]	2.47 (10.032)	-33.87 (10.032)	10.87 (4.187)	-21.03 (3.061)	
95% CI [2]	-20.66, 25.61	-57.01, -10.74	2.61, 19.13	-27.07, -14.99	
Difference (95% CI) in CFB [2]		-36.35 (-65.94, -6.75)		-31.90 (-41.18, -22.61)	
p-value [3]		0.022		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-thpy-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.1.8a
Change from Baseline in Serum Tryptase (ng/mL) by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	119	
Mean (StdDev)	53.10 (52.875)	21.27 (15.108)	74.48 (91.709)	29.74 (39.484)	
Median	38.50	18.80	36.95	14.50	
Min, Max	6.4, 129.0	7.3, 55.0	5.3, 554.4	2.0, 183.2	
C6D1 CFB					
n	4	9	58	119	
LS Mean (StdErr) [2]	1.57 (10.658)	-33.17 (10.658)	10.97 (4.344)	-21.24 (3.283)	
95% CI [2]	-22.54, 25.68	-57.28, -9.06	2.40, 19.55	-27.72, -14.76	
Difference (95% CI) in CFB [2]		-34.75 (-65.49, -4.00)		-32.22 (-41.90, -22.53)	
p-value [3]		0.031		<0.0001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-thpy-a.sas Date: 15:41/07AUG2023

Table 35.2.3.2.1.8a
Change from Baseline in Serum Tryptase (ng/mL) by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	9	60	125	
Mean (StdDev)	55.20 (55.017)	19.33 (13.935)	76.62 (102.677)	32.16 (44.808)	
Median	40.45	17.90	38.95	14.30	
Min, Max	5.9, 134.0	7.1, 53.3	5.5, 590.4	2.1, 234.4	
C7D1 CFB					
n	4	9	60	125	
LS Mean (StdErr) [2]	3.43 (11.666)	-37.16 (11.666)	15.03 (5.380)	-21.45 (4.051)	
95% CI [2]	-22.96, 29.82	-63.55, -10.77	4.42, 25.65	-29.44, -13.45	
Difference (95% CI) in CFB [2]		-40.59 (-74.24, -6.94)		-36.48 (-48.37, -24.59)	
Hedges'G (95% CI) in CFB		-1.17 (-2.87, 0.01)		-0.82 (-1.15, -0.51)	
p-value [3]		0.023		<0.0001	
					0.705

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-sum-g-itt-thpy-a.sas Date: 15:41/07AUG2023

Table 35.2.3.3.1a
Summary of Serum Tryptase at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in Serum Tryptase	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	0/ 71 (0.0) (0.0, 5.1)	76/141 (53.9) (45.3, 62.3)	NE (30.59, NE) <0.0001	NE (NE, NE) NE	0.55 (0.47, 0.64) <0.0001	
Age Group (Years)						0.998
< 65	0/ 60 (0.0) (0.0, 6.0)	69/132 (52.3) (43.4, 61.0)	NE (23.28, NE) <0.0001	NE (NE, NE) NE	0.53 (0.44, 0.62) <0.0001	
>= 65	0/ 11 (0.0) (0.0, 28.5)	7/ 9 (77.8) (40.0, 97.2)	NE (2.95, NE) 0.001	NE (NE, NE) NE	0.75 (0.43, 1.00) <0.0001	
Sex						>0.999
Male	0/ 17 (0.0) (0.0, 19.5)	22/ 41 (53.7) (37.4, 69.3)	NE (5.65, NE) <0.0001	NE (NE, NE) NE	0.55 (0.40, 0.70) <0.0001	
Female	0/ 54 (0.0) (0.0, 6.6)	54/100 (54.0) (43.7, 64.0)	NE (23.77, NE) <0.0001	NE (NE, NE) NE	0.56 (0.46, 0.65) <0.0001	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-resp-itt-a.sas Date: 17:59/13APR2023

Table 35.2.3.3.1a
Summary of Serum Tryptase at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in Serum Tryptase	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Region						>0.999
North America	0/ 33 (0.0) (0.0, 10.6)	31/ 60 (51.7) (38.4, 64.8)	NE (13.61, NE) <0.0001	NE (NE, NE) NE	0.56 (0.43, 0.69) <0.0001	
Europe	0/ 38 (0.0) (0.0, 9.3)	45/ 81 (55.6) (44.1, 66.6)	NE (14.30, NE) <0.0001	NE (NE, NE) NE	0.56 (0.45, 0.66) <0.0001	
Country						>0.999
BEL	0/ 1 (0.0) (0.0, 97.5)	1/ 3 (33.3) (0.8, 90.6)	NE (NE, NE) NE	NE (NE, NE) NE	0.00 (0.00, 0.00) NE	
CAN	0/ 5 (0.0) (0.0, 52.2)	5/ 8 (62.5) (24.5, 91.5)	NE (0.88, NE) 0.035	NE (NE, NE) NE	0.84 (0.64, 1.00) <0.0001	
CHE	0/ 1 (0.0) (0.0, 97.5)	0/ 2 (0.0) (0.0, 84.2)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DEU	0/ 15 (0.0) (0.0, 21.8)	10/ 19 (52.6) (28.9, 75.6)	NE (3.21, NE) 0.001	NE (NE, NE) NE	0.51 (0.28, 0.74) <0.0001	
DNK	0/0	0/ 1 (0.0) (0.0, 97.5)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-resp-itt-a.sas Date: 17:59/13APR2023

Table 35.2.3.3.1a
Summary of Serum Tryptase at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in Serum Tryptase	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
ESP	0/ 3 (0.0)	9/ 14 (64.3)	NE	NE	0.67	
	(0.0, 70.8)	(35.1, 87.2)	(0.70, NE)	(NE, NE)	(0.39, 0.94)	
			0.056	NE	<0.0001	
FRA	0/ 6 (0.0)	6/ 11 (54.5)	NE	NE	0.47	
	(0.0, 45.9)	(23.4, 83.3)	(0.63, NE)	(NE, NE)	(0.08, 0.85)	
			0.069	NE	0.017	
GBR	0/ 5 (0.0)	7/ 11 (63.6)	NE	NE	0.57	
	(0.0, 52.2)	(30.8, 89.1)	(0.82, NE)	(NE, NE)	(0.24, 0.91)	
			0.052	NE	<0.001	
ITA	0/0	2/ 4 (50.0)	NE	NE	NE	
		(6.8, 93.2)	(NE, NE)	(NE, NE)	(NE, NE)	
			NE	NE	NE	
NLD	0/ 3 (0.0)	5/ 9 (55.6)	NE	NE	0.33	
	(0.0, 70.8)	(21.2, 86.3)	(0.05, NE)	(NE, NE)	(-0.20, 0.87)	
			0.317	NE	0.221	
NOR	0/ 3 (0.0)	5/ 5 (100.0)	NE	NE	1.00	
	(0.0, 70.8)	(47.8, 100.0)	(1.25, NE)	(NE, NE)	(1.00, 1.00)	
			0.014	NE	NE	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-resp-itt-a.sas Date: 17:59/13APR2023

Table 35.2.3.3.1a
Summary of Serum Tryptase at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in Serum Tryptase	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
SWE	0/ 1 (0.0) (0.0, 97.5)	0/ 2 (0.0) (0.0, 84.2)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
USA	0/ 28 (0.0) (0.0, 12.3)	26/ 52 (50.0) (35.8, 64.2)	NE (9.89, NE) <0.0001	NE (NE, NE) NE	0.52 (0.37, 0.66) <0.0001	
Baseline ISM Status						>0.999
Moderate	0/ 26 (0.0) (0.0, 13.2)	29/ 52 (55.8) (41.3, 69.5)	NE (13.07, NE) <0.0001	NE (NE, NE) NE	0.59 (0.46, 0.72) <0.0001	
Severe	0/ 45 (0.0) (0.0, 7.9)	47/ 87 (54.0) (43.0, 64.8)	NE (15.42, NE) <0.0001	NE (NE, NE) NE	0.53 (0.43, 0.64) <0.0001	
Baseline Serum Tryptase (ng/mL)						0.997
< 20	0/ 15 (0.0) (0.0, 21.8)	7/ 28 (25.0) (10.7, 44.9)	NE (1.44, NE) 0.021	NE (NE, NE) NE	0.28 (0.12, 0.45) <0.001	
>= 20	0/ 56 (0.0) (0.0, 6.4)	69/113 (61.1) (51.4, 70.1)	NE (28.38, NE) <0.0001	NE (NE, NE) NE	0.62 (0.53, 0.71) <0.0001	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-resp-itt-a.sas Date: 17:59/13APR2023

Table 35.2.3.3.1a
Summary of Serum Tryptase at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in Serum Tryptase	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.999
0 or 1	0/ 67 (0.0) (0.0, 5.4)	72/131 (55.0) (46.0, 63.7)	NE (30.59, NE) <0.0001	NE (NE, NE) NE	0.57 (0.48, 0.65) <0.0001	
2+	0/ 4 (0.0) (0.0, 60.2)	4/ 10 (40.0) (12.2, 73.8)	NE (0.37, NE) 0.151	NE (NE, NE) NE	0.43 (0.09, 0.76) 0.013	
Prior TKI therapy						>0.999
Yes	0/ 4 (0.0) (0.0, 60.2)	5/ 10 (50.0) (18.7, 81.3)	NE (0.41, NE) 0.090	NE (NE, NE) NE	0.53 (0.19, 0.86) 0.002	
No	0/ 67 (0.0) (0.0, 5.4)	71/131 (54.2) (45.3, 62.9)	NE (28.53, NE) <0.0001	NE (NE, NE) NE	0.56 (0.47, 0.64) <0.0001	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-tryp-resp-itt-a.sas Date: 17:59/13APR2023

Table 35.2.4.1.1.2a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	17	41	54	100	
Mean (StdDev)	4.752 (8.2125)	1.889 (4.4739)	3.198 (7.3972)	2.849 (6.6902)	
Median	0.390	0.420	0.225	0.340	
Min, Max	0.00, 25.64	0.00, 26.54	0.01, 36.74	0.00, 41.29	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-sex-a.sas Date: 15:42/07AUG2023

Table 35.2.4.1.1.2a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	15	39	50	93	
Mean (StdDev)	5.233 (8.2174)	1.510 (3.6968)	3.208 (7.6327)	2.047 (5.5414)	
Median	0.410	0.430	0.215	0.240	
Min, Max	0.01, 23.50	0.00, 21.77	0.01, 37.24	0.00, 37.93	
C2D1 CFB					
n	15	39	50	93	
LS Mean (StdErr) [2]	-0.01 (0.228)	-0.36 (0.150)	0.04 (0.156)	-0.41 (0.127)	
95% CI [2]	-0.46, 0.45	-0.66, -0.06	-0.27, 0.35	-0.66, -0.16	
Difference (95% CI) in CFB [2]		-0.35 (-0.87, 0.17)		-0.45 (-0.79, -0.11)	
p-value [3]		0.178		0.011	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-sex-a.sas Date: 15:42/07AUG2023

Table 35.2.4.1.1.2a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	40	45	96	
Mean (StdDev)	4.925 (8.5201)	1.126 (3.1673)	3.036 (7.3924)	1.975 (5.4892)	
Median	0.440	0.195	0.240	0.185	
Min, Max	0.01, 26.07	0.00, 19.05	0.00, 36.89	0.00, 36.99	
C3D1 CFB					
n	17	40	45	96	
LS Mean (StdErr) [2]	0.30 (0.306)	-0.60 (0.211)	0.20 (0.260)	-0.76 (0.202)	
95% CI [2]	-0.31, 0.92	-1.02, -0.18	-0.31, 0.71	-1.16, -0.36	
Difference (95% CI) in CFB [2]		-0.91 (-1.60, -0.21)		-0.96 (-1.53, -0.39)	
p-value [3]		0.012		0.001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-sex-a.sas Date: 15:42/07AUG2023

Table 35.2.4.1.1.2a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	14	37	46	94	
Mean (StdDev)	5.651 (8.7682)	0.962 (2.4994)	2.408 (6.2471)	1.818 (5.1747)	
Median	0.410	0.170	0.150	0.140	
Min, Max	0.01, 24.59	0.00, 14.34	0.00, 34.76	0.00, 38.21	
C4D1 CFB					
n	14	37	46	94	
LS Mean (StdErr) [2]	0.13 (0.524)	-0.78 (0.350)	0.20 (0.322)	-0.99 (0.252)	
95% CI [2]	-0.93, 1.18	-1.49, -0.08	-0.44, 0.84	-1.48, -0.49	
Difference (95% CI) in CFB [2]		-0.91 (-2.12, 0.29)		-1.18 (-1.88, -0.49)	
p-value [3]		0.134		0.001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-sex-a.sas Date: 15:42/07AUG2023

Table 35.2.4.1.1.2a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	15	36	43	92	
Mean (StdDev)	3.849 (7.0594)	0.901 (2.3439)	1.780 (4.5319)	1.707 (5.1234)	
Median	0.420	0.130	0.170	0.140	
Min, Max	0.00, 25.53	0.00, 12.98	0.00, 26.39	0.00, 37.64	
C5D1 CFB					
n	15	36	43	92	
LS Mean (StdErr) [2]	0.21 (0.547)	-0.80 (0.370)	0.27 (0.363)	-1.03 (0.283)	
95% CI [2]	-0.89, 1.31	-1.54, -0.05	-0.45, 0.99	-1.59, -0.47	
Difference (95% CI) in CFB [2]		-1.01 (-2.27, 0.26)		-1.30 (-2.10, -0.50)	
p-value [3]		0.116		0.002	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-sex-a.sas Date: 15:42/07AUG2023

Table 35.2.4.1.1.2a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	46	89	
Mean (StdDev)	5.397 (8.6120)	0.801 (1.9697)	3.080 (7.4713)	1.639 (5.1978)	
Median	0.390	0.155	0.260	0.110	
Min, Max	0.00, 25.18	0.00, 10.65	0.00, 38.37	0.00, 37.19	
C6D1 CFB					
n	15	38	46	89	
LS Mean (StdErr) [2]	0.32 (0.631)	-0.77 (0.420)	0.10 (0.324)	-0.93 (0.258)	
95% CI [2]	-0.95, 1.59	-1.61, 0.08	-0.54, 0.74	-1.44, -0.42	
Difference (95% CI) in CFB [2]		-1.09 (-2.49, 0.31)		-1.03 (-1.75, -0.31)	
p-value [3]		0.124		0.005	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-sex-a.sas Date: 15:42/07AUG2023

Table 35.2.4.1.1.2a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	17	40	45	92	
Mean (StdDev)	4.759 (8.1268)	0.778 (1.5069)	2.480 (5.9222)	1.873 (5.3277)	
Median	0.380	0.195	0.210	0.105	
Min, Max	0.00, 24.24	0.00, 7.17	0.00, 28.10	0.00, 38.22	
C7D1 CFB					
n	17	40	45	92	
LS Mean (StdErr) [2]	0.25 (0.675)	-0.89 (0.465)	0.32 (0.355)	-1.02 (0.282)	
95% CI [2]	-1.11, 1.60	-1.82, 0.04	-0.38, 1.02	-1.58, -0.47	
Difference (95% CI) in CFB [2]		-1.14 (-2.67, 0.40)		-1.34 (-2.12, -0.56)	
Hedges'G (95% CI) in CFB		-0.39 (-0.99, 0.18)		-0.51 (-0.89, -0.16)	
p-value [3]		0.143		<0.001	
					0.835

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-sex-a.sas Date: 15:42/07AUG2023

Table 35.2.4.1.1.3a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	33	60	38	81	
Mean (StdDev)	3.772 (8.2510)	2.879 (6.3993)	3.395 (7.0316)	2.341 (5.9502)	
Median	0.270	0.430	0.220	0.290	
Min, Max	0.01, 36.74	0.00, 41.29	0.00, 25.69	0.00, 29.12	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-reg-a.sas Date: 15:42/07AUG2023

Table 35.2.4.1.1.3a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	28	57	37	75	
Mean (StdDev)	4.309 (8.9232)	2.220 (5.6323)	3.196 (6.8267)	1.635 (4.5983)	
Median	0.325	0.290	0.210	0.210	
Min, Max	0.01, 37.24	0.00, 37.93	0.01, 24.98	0.00, 26.14	
C2D1 CFB					
n	28	57	37	75	
LS Mean (StdErr) [2]	0.15 (0.201)	-0.50 (0.157)	-0.11 (0.158)	-0.36 (0.119)	
95% CI [2]	-0.25, 0.55	-0.82, -0.19	-0.42, 0.21	-0.60, -0.12	
Difference (95% CI) in CFB [2]		-0.66 (-1.12, -0.20)		-0.25 (-0.60, 0.10)	
p-value [3]		0.006		0.153	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-reg-a.sas Date: 15:42/07AUG2023

Table 35.2.4.1.1.3a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	26	58	36	78	
Mean (StdDev)	4.420 (9.3615)	1.787 (5.2397)	2.929 (6.2916)	1.680 (4.7107)	
Median	0.345	0.230	0.245	0.145	
Min, Max	0.00, 36.89	0.00, 36.99	0.00, 26.07	0.00, 27.54	
C3D1 CFB					
n	26	58	36	78	
LS Mean (StdErr) [2]	0.30 (0.333)	-0.87 (0.252)	0.11 (0.250)	-0.67 (0.183)	
95% CI [2]	-0.36, 0.96	-1.37, -0.36	-0.38, 0.61	-1.04, -0.31	
Difference (95% CI) in CFB [2]		-1.16 (-1.92, -0.40)		-0.79 (-1.34, -0.24)	
p-value [3]		0.003		0.006	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-reg-a.sas Date: 15:42/07AUG2023

Table 35.2.4.1.1.3a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	24	54	36	77	
Mean (StdDev)	3.617 (8.1897)	1.828 (5.4848)	2.863 (6.1359)	1.400 (3.8634)	
Median	0.155	0.205	0.240	0.120	
Min, Max	0.00, 34.76	0.00, 38.21	0.00, 24.59	0.00, 23.14	
C4D1 CFB					
n	24	54	36	77	
LS Mean (StdErr) [2]	0.26 (0.385)	-0.99 (0.295)	0.08 (0.365)	-0.97 (0.266)	
95% CI [2]	-0.51, 1.02	-1.58, -0.40	-0.64, 0.80	-1.49, -0.44	
Difference (95% CI) in CFB [2]		-1.24 (-2.11, -0.38)		-1.05 (-1.85, -0.24)	
p-value [3]		0.005		0.011	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-reg-a.sas Date: 15:42/07AUG2023

Table 35.2.4.1.1.3a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	24	51	34	77	
Mean (StdDev)	2.312 (5.6218)	1.721 (5.4865)	2.318 (5.1668)	1.320 (3.7831)	
Median	0.210	0.140	0.185	0.140	
Min, Max	0.00, 26.39	0.00, 37.64	0.00, 25.53	0.00, 24.06	
C5D1 CFB					
n	24	51	34	77	
LS Mean (StdErr) [2]	0.45 (0.444)	-1.11 (0.334)	0.04 (0.398)	-0.96 (0.291)	
95% CI [2]	-0.44, 1.33	-1.78, -0.45	-0.75, 0.83	-1.54, -0.38	
Difference (95% CI) in CFB [2]		-1.56 (-2.58, -0.54)		-1.00 (-1.88, -0.12)	
p-value [3]		0.003		0.026	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-reg-a.sas Date: 15:42/07AUG2023

Table 35.2.4.1.1.3a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	28	51	33	76	
Mean (StdDev)	4.315 (9.2127)	1.468 (5.3208)	3.085 (6.3649)	1.335 (3.8706)	
Median	0.335	0.140	0.240	0.115	
Min, Max	0.00, 38.37	0.00, 37.19	0.00, 25.18	0.00, 25.86	
C6D1 CFB					
n	28	51	33	76	
LS Mean (StdErr) [2]	0.21 (0.344)	-0.82 (0.278)	0.08 (0.436)	-0.98 (0.313)	
95% CI [2]	-0.48, 0.89	-1.37, -0.27	-0.78, 0.94	-1.60, -0.36	
Difference (95% CI) in CFB [2]		-1.03 (-1.81, -0.24)		-1.06 (-2.02, -0.10)	
p-value [3]		0.011		0.030	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-reg-a.sas Date: 15:42/07AUG2023

Table 35.2.4.1.1.3a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	28	58	34	74	
Mean (StdDev)	3.262 (7.1816)	1.810 (5.4544)	2.976 (6.2041)	1.331 (3.7043)	
Median	0.300	0.195	0.235	0.105	
Min, Max	0.00, 28.10	0.00, 38.22	0.00, 24.24	0.00, 24.80	
C7D1 CFB					
n	28	58	34	74	
LS Mean (StdErr) [2]	0.48 (0.378)	-0.94 (0.292)	0.02 (0.479)	-1.09 (0.354)	
95% CI [2]	-0.27, 1.24	-1.52, -0.36	-0.93, 0.97	-1.79, -0.39	
Difference (95% CI) in CFB [2]		-1.43 (-2.28, -0.58)		-1.11 (-2.17, -0.05)	
Hedges'G (95% CI) in CFB		-0.66 (-1.14, -0.21)		-0.37 (-0.79, 0.03)	
p-value [3]		0.001		0.040	
					0.693

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-reg-a.sas Date: 15:42/07AUG2023

Table 35.2.4.1.1.4a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-cou-a.sas Date: 15:42/07AUG2023

Table 35.2.4.1.1.4a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-cou-a.sas Date: 15:42/07AUG2023

Table 35.2.4.1.1.4a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-cou-a.sas Date: 15:42/07AUG2023

Table 35.2.4.1.1.4a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-cou-a.sas Date: 15:42/07AUG2023

Table 35.2.4.1.1.4a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-cou-a.sas Date: 15:42/07AUG2023

Table 35.2.4.1.1.5a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	26	52	45	87	
Mean (StdDev)	4.363 (8.1868)	2.678 (6.3648)	3.112 (7.2442)	2.463 (6.0534)	
Median	0.500	0.290	0.230	0.420	
Min, Max	0.00, 25.69	0.00, 29.12	0.01, 36.74	0.00, 41.29	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-ism-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.1.5a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	22	49	43	81	
Mean (StdDev)	4.550 (8.3076)	2.351 (5.5390)	3.228 (7.5159)	1.575 (4.7965)	
Median	0.815	0.250	0.210	0.230	
Min, Max	0.01, 24.98	0.00, 26.14	0.01, 37.24	0.00, 37.93	
C2D1 CFB					
n	22	49	43	81	
LS Mean (StdErr) [2]	-0.11 (0.248)	-0.35 (0.172)	0.11 (0.141)	-0.43 (0.114)	
95% CI [2]	-0.61, 0.38	-0.70, -0.01	-0.17, 0.38	-0.66, -0.20	
Difference (95% CI) in CFB [2]		-0.24 (-0.79, 0.31)		-0.54 (-0.86, -0.21)	
p-value [3]		0.384		0.001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-ism-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.1.5a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	52	40	82	
Mean (StdDev)	3.826 (7.4938)	1.927 (5.2006)	3.405 (7.8905)	1.581 (4.8191)	
Median	0.525	0.125	0.245	0.205	
Min, Max	0.01, 26.07	0.00, 27.54	0.00, 36.89	0.00, 36.99	
C3D1 CFB					
n	22	52	40	82	
LS Mean (StdErr) [2]	0.20 (0.290)	-0.59 (0.198)	0.19 (0.268)	-0.86 (0.209)	
95% CI [2]	-0.38, 0.78	-0.98, -0.19	-0.34, 0.72	-1.27, -0.44	
Difference (95% CI) in CFB [2]		-0.79 (-1.42, -0.15)		-1.05 (-1.67, -0.43)	
p-value [3]		0.016		0.001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-ism-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.1.5a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	19	50	41	79	
Mean (StdDev)	2.980 (5.9005)	1.650 (4.3000)	3.250 (7.4848)	1.503 (4.8232)	
Median	0.180	0.125	0.170	0.140	
Min, Max	0.01, 24.59	0.00, 23.14	0.00, 34.76	0.00, 38.21	
C4D1 CFB					
n	19	50	41	79	
LS Mean (StdErr) [2]	0.19 (0.503)	-0.86 (0.344)	0.16 (0.309)	-1.00 (0.242)	
95% CI [2]	-0.81, 1.19	-1.55, -0.18	-0.45, 0.77	-1.48, -0.52	
Difference (95% CI) in CFB [2]		-1.05 (-2.16, 0.05)		-1.16 (-1.87, -0.45)	
p-value [3]		0.061		0.002	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-ism-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.1.5a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	21	49	37	77	
Mean (StdDev)	2.807 (5.7489)	1.489 (4.3114)	2.036 (5.1069)	1.452 (4.7240)	
Median	0.680	0.100	0.130	0.150	
Min, Max	0.00, 25.53	0.00, 24.06	0.00, 26.39	0.00, 37.64	
C5D1 CFB					
n	21	49	37	77	
LS Mean (StdErr) [2]	0.15 (0.504)	-0.82 (0.343)	0.29 (0.367)	-1.11 (0.284)	
95% CI [2]	-0.85, 1.16	-1.51, -0.14	-0.43, 1.02	-1.67, -0.55	
Difference (95% CI) in CFB [2]		-0.98 (-2.09, 0.14)		-1.40 (-2.25, -0.56)	
p-value [3]		0.085		0.001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-ism-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.1.5a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	46	38	79	
Mean (StdDev)	3.420 (6.4636)	1.657 (4.5524)	3.788 (8.5264)	1.211 (4.5185)	
Median	0.390	0.095	0.260	0.140	
Min, Max	0.00, 23.70	0.00, 25.86	0.00, 38.37	0.00, 37.19	
C6D1 CFB					
n	23	46	38	79	
LS Mean (StdErr) [2]	-0.02 (0.545)	-0.84 (0.394)	0.33 (0.321)	-0.88 (0.244)	
95% CI [2]	-1.11, 1.06	-1.63, -0.05	-0.31, 0.97	-1.36, -0.40	
Difference (95% CI) in CFB [2]		-0.82 (-2.03, 0.40)		-1.21 (-1.94, -0.48)	
p-value [3]		0.183		0.001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-ism-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.1.5a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	23	52	39	78	
Mean (StdDev)	3.703 (7.2754)	1.485 (4.0453)	2.752 (6.2543)	1.556 (4.9140)	
Median	0.820	0.100	0.210	0.140	
Min, Max	0.00, 26.72	0.00, 24.80	0.00, 28.10	0.00, 38.22	
C7D1 CFB					
n	23	52	39	78	
LS Mean (StdErr) [2]	0.23 (0.605)	-0.92 (0.420)	0.34 (0.348)	-1.07 (0.277)	
95% CI [2]	-0.97, 1.44	-1.75, -0.08	-0.35, 1.03	-1.62, -0.52	
Difference (95% CI) in CFB [2]		-1.15 (-2.48, 0.18)		-1.41 (-2.21, -0.61)	
Hedges'G (95% CI) in CFB		-0.38 (-0.90, 0.11)		-0.59 (-1.00, -0.21)	
p-value [3]		0.089		<0.001	
					0.723

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-ism-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.1.6a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	15	28	56	113	
Mean (StdDev)	0.155 (0.1564)	0.917 (2.5394)	4.484 (8.2994)	2.980 (6.6742)	
Median	0.110	0.145	0.575	0.440	
Min, Max	0.00, 0.42	0.00, 12.00	0.01, 36.74	0.00, 41.29	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-tryp-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.1.6a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	50	105	
Mean (StdDev)	0.167 (0.1717)	0.393 (1.1011)	4.728 (8.5795)	2.272 (5.5858)	
Median	0.120	0.070	0.815	0.320	
Min, Max	0.01, 0.47	0.00, 5.79	0.01, 37.24	0.00, 37.93	
C2D1 CFB					
n	15	27	50	105	
LS Mean (StdErr) [2]	0.03 (0.054)	-0.11 (0.039)	-0.10 (0.152)	-0.62 (0.107)	
95% CI [2]	-0.08, 0.14	-0.19, -0.03	-0.40, 0.20	-0.83, -0.41	
Difference (95% CI) in CFB [2]		-0.14 (-0.27, -0.00)		-0.51 (-0.87, -0.15)	
p-value [3]		0.044		0.005	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-tryp-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.1.6a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	28	47	108	
Mean (StdDev)	0.169 (0.1728)	0.601 (1.9131)	4.635 (8.5755)	2.017 (5.4091)	
Median	0.100	0.070	0.780	0.230	
Min, Max	0.00, 0.44	0.00, 9.71	0.00, 36.89	0.00, 36.99	
C3D1 CFB					
n	15	28	47	108	
LS Mean (StdErr) [2]	0.07 (0.160)	-0.30 (0.114)	0.11 (0.242)	-1.02 (0.163)	
95% CI [2]	-0.26, 0.39	-0.53, -0.07	-0.37, 0.58	-1.34, -0.70	
Difference (95% CI) in CFB [2]		-0.37 (-0.76, 0.02)		-1.12 (-1.69, -0.55)	
p-value [3]		0.065		<0.001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-tryp-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.1.6a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	14	26	46	105	
Mean (StdDev)	0.174 (0.2057)	0.568 (1.7298)	4.075 (7.7527)	1.826 (5.0257)	
Median	0.080	0.090	0.305	0.180	
Min, Max	0.00, 0.63	0.00, 8.43	0.00, 34.76	0.00, 38.21	
C4D1 CFB					
n	14	26	46	105	
LS Mean (StdErr) [2]	0.08 (0.216)	-0.38 (0.156)	-0.01 (0.318)	-1.32 (0.212)	
95% CI [2]	-0.36, 0.52	-0.70, -0.07	-0.64, 0.62	-1.74, -0.90	
Difference (95% CI) in CFB [2]		-0.47 (-0.99, 0.06)		-1.31 (-2.05, -0.57)	
p-value [3]		0.081		<0.001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-tryp-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.1.6a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	27	44	101	
Mean (StdDev)	0.166 (0.2103)	0.496 (1.5628)	2.999 (5.9494)	1.743 (5.0011)	
Median	0.060	0.050	0.255	0.160	
Min, Max	0.00, 0.66	0.00, 7.77	0.00, 26.39	0.00, 37.64	
C5D1 CFB					
n	14	27	44	101	
LS Mean (StdErr) [2]	0.08 (0.243)	-0.41 (0.170)	0.10 (0.358)	-1.37 (0.242)	
95% CI [2]	-0.41, 0.58	-0.75, -0.06	-0.61, 0.80	-1.85, -0.89	
Difference (95% CI) in CFB [2]		-0.49 (-1.09, 0.10)		-1.47 (-2.31, -0.62)	
p-value [3]		0.101		<0.001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-tryp-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.1.6a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	13	27	48	100	
Mean (StdDev)	0.153 (0.1832)	0.506 (1.6122)	4.596 (8.5160)	1.626 (4.9700)	
Median	0.060	0.100	0.590	0.155	
Min, Max	0.00, 0.47	0.00, 8.20	0.00, 38.37	0.00, 37.19	
C6D1 CFB					
n	13	27	48	100	
LS Mean (StdErr) [2]	0.08 (0.256)	-0.41 (0.175)	0.01 (0.330)	-1.21 (0.236)	
95% CI [2]	-0.44, 0.60	-0.77, -0.06	-0.64, 0.66	-1.67, -0.74	
Difference (95% CI) in CFB [2]		-0.49 (-1.11, 0.12)		-1.22 (-2.01, -0.43)	
p-value [3]		0.113		0.003	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-tryp-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.1.6a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	14	26	48	106	
Mean (StdDev)	0.188 (0.2173)	0.527 (1.7036)	3.956 (7.3070)	1.790 (4.9752)	
Median	0.080	0.065	0.590	0.205	
Min, Max	0.00, 0.57	0.00, 8.44	0.00, 28.10	0.00, 38.22	
C7D1 CFB					
n	14	26	48	106	
LS Mean (StdErr) [2]	0.11 (0.232)	-0.41 (0.165)	0.13 (0.368)	-1.39 (0.253)	
95% CI [2]	-0.36, 0.58	-0.75, -0.08	-0.59, 0.86	-1.89, -0.89	
Difference (95% CI) in CFB [2]		-0.52 (-1.09, 0.05)		-1.52 (-2.39, -0.65)	
Hedges'G (95% CI) in CFB		-0.60 (-1.32, 0.05)		-0.59 (-0.94, -0.24)	
p-value [3]		0.073		<0.001	
					0.208

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-tryp-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.1.7a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	67	131	4	10	
Mean (StdDev)	3.706 (7.7564)	2.308 (5.6927)	1.298 (2.4418)	5.999 (10.1050)	
Median	0.270	0.320	0.095	0.730	
Min, Max	0.00, 36.74	0.00, 41.29	0.04, 4.96	0.01, 29.12	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-ecog-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.1.7a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	61	124	4	8	
Mean (StdDev)	3.832 (7.9634)	1.611 (4.5371)	1.283 (2.4451)	6.180 (9.7347)	
Median	0.270	0.235	0.070	0.560	
Min, Max	0.01, 37.24	0.00, 37.93	0.04, 4.95	0.00, 26.14	
C2D1 CFB					
n	61	124	4	8	
LS Mean (StdErr) [2]	-0.00 (0.128)	-0.37 (0.097)	0.61 (0.937)	-0.71 (0.739)	
95% CI [2]	-0.25, 0.25	-0.57, -0.18	-1.55, 2.78	-2.42, 0.99	
Difference (95% CI) in CFB [2]		-0.37 (-0.66, -0.09)		-1.33 (-3.21, 0.55)	
p-value [3]		0.011		0.142	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-ecog-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.1.7a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	58	127	4	9	
Mean (StdDev)	3.706 (7.9135)	1.474 (4.3878)	1.353 (2.5651)	5.278 (9.5297)	
Median	0.270	0.160	0.085	0.300	
Min, Max	0.00, 36.89	0.00, 36.99	0.04, 5.20	0.01, 27.54	
C3D1 CFB					
n	58	127	4	9	
LS Mean (StdErr) [2]	0.19 (0.209)	-0.73 (0.155)	0.93 (1.165)	-0.45 (0.887)	
95% CI [2]	-0.22, 0.60	-1.03, -0.42	-1.71, 3.56	-2.46, 1.56	
Difference (95% CI) in CFB [2]		-0.91 (-1.38, -0.45)		-1.38 (-3.58, 0.83)	
p-value [3]		<0.001		0.191	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-ecog-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.1.7a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	123	4	8	
Mean (StdDev)	3.288 (7.1775)	1.366 (4.2134)	1.443 (2.7317)	4.805 (8.2808)	
Median	0.215	0.140	0.085	0.310	
Min, Max	0.00, 34.76	0.00, 38.21	0.06, 5.54	0.00, 23.14	
C4D1 CFB					
n	56	123	4	8	
LS Mean (StdErr) [2]	0.12 (0.268)	-0.90 (0.198)	1.76 (2.148)	-1.18 (1.624)	
95% CI [2]	-0.41, 0.64	-1.29, -0.51	-3.20, 6.71	-4.93, 2.56	
Difference (95% CI) in CFB [2]		-1.01 (-1.61, -0.42)		-2.94 (-7.13, 1.25)	
p-value [3]		<0.001		0.144	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-ecog-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.1.7a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	55	119	3	9	
Mean (StdDev)	2.344 (5.4254)	1.263 (4.1175)	1.787 (2.9561)	4.343 (8.0456)	
Median	0.200	0.140	0.100	0.370	
Min, Max	0.00, 26.39	0.00, 37.64	0.06, 5.20	0.00, 24.06	
C5D1 CFB					
n	55	119	3	9	
LS Mean (StdErr) [2]	0.20 (0.297)	-0.94 (0.220)	1.67 (2.554)	-0.99 (1.772)	
95% CI [2]	-0.38, 0.79	-1.37, -0.50	-4.22, 7.56	-5.08, 3.10	
Difference (95% CI) in CFB [2]		-1.14 (-1.81, -0.47)		-2.66 (-7.56, 2.23)	
p-value [3]		<0.001		0.245	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-ecog-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.1.7a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	57	118	4	9	
Mean (StdDev)	3.805 (7.9815)	1.149 (3.9880)	1.430 (2.7333)	4.520 (8.5433)	
Median	0.340	0.110	0.065	0.360	
Min, Max	0.00, 38.37	0.00, 37.19	0.06, 5.53	0.00, 25.86	
C6D1 CFB					
n	57	118	4	9	
LS Mean (StdErr) [2]	0.09 (0.285)	-0.84 (0.214)	1.38 (2.211)	-1.01 (1.752)	
95% CI [2]	-0.47, 0.66	-1.27, -0.42	-3.62, 6.38	-4.97, 2.96	
Difference (95% CI) in CFB [2]		-0.94 (-1.58, -0.30)		-2.39 (-6.70, 1.93)	
p-value [3]		0.004		0.242	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-ecog-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.1.7a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	59	123	3	9	
Mean (StdDev)	3.167 (6.7461)	1.327 (4.1128)	1.890 (3.1438)	4.474 (8.3527)	
Median	0.260	0.130	0.100	0.300	
Min, Max	0.00, 28.10	0.00, 38.22	0.05, 5.52	0.00, 24.80	
C7D1 CFB					
n	59	123	3	9	
LS Mean (StdErr) [2]	0.24 (0.318)	-0.97 (0.242)	1.71 (2.335)	-0.88 (1.620)	
95% CI [2]	-0.39, 0.87	-1.45, -0.49	-3.68, 7.09	-4.62, 2.85	
Difference (95% CI) in CFB [2]		-1.21 (-1.92, -0.50)		-2.59 (-7.07, 1.89)	
Hedges'G (95% CI) in CFB		-0.46 (-0.78, -0.15)		-0.51 (-2.15, 0.87)	
p-value [3]		0.001		0.219	
					0.471

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-ecog-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.1.8a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	67	131	
Mean (StdDev)	3.260 (4.8926)	5.149 (12.8807)	3.588 (7.7246)	2.373 (5.3304)	
Median	1.280	0.420	0.230	0.340	
Min, Max	0.03, 10.45	0.01, 41.29	0.00, 36.74	0.00, 29.12	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-thpy-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.1.8a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	9	61	123	
Mean (StdDev)	3.433 (5.3011)	5.074 (12.4613)	3.691 (7.9191)	1.655 (4.0609)	
Median	1.230	0.290	0.220	0.250	
Min, Max	0.02, 11.25	0.01, 37.93	0.01, 37.24	0.00, 26.14	
C2D1 CFB					
n	4	9	61	123	
LS Mean (StdErr) [2]	0.13 (0.569)	-0.65 (0.569)	0.01 (0.132)	-0.39 (0.100)	
95% CI [2]	-1.16, 1.41	-1.93, 0.64	-0.25, 0.27	-0.58, -0.19	
Difference (95% CI) in CFB [2]		-0.77 (-2.41, 0.87)		-0.39 (-0.69, -0.10)	
p-value [3]		0.314		0.009	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-thpy-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.1.8a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	58	126	
Mean (StdDev)	3.305 (5.0210)	4.227 (11.5658)	3.571 (7.8741)	1.527 (4.0026)	
Median	1.250	0.250	0.245	0.170	
Min, Max	0.03, 10.69	0.00, 36.99	0.00, 36.89	0.00, 27.54	
C3D1 CFB					
n	4	10	58	126	
LS Mean (StdErr) [2]	-0.14 (0.769)	-1.09 (0.769)	0.23 (0.211)	-0.71 (0.157)	
95% CI [2]	-1.85, 1.57	-2.80, 0.62	-0.19, 0.65	-1.02, -0.40	
Difference (95% CI) in CFB [2]		-0.95 (-3.13, 1.23)		-0.94 (-1.41, -0.47)	
p-value [3]		0.354		<0.001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-thpy-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.1.8a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	122	
Mean (StdDev)	3.717 (6.1195)	4.739 (12.5984)	3.135 (7.0618)	1.343 (3.3627)	
Median	0.360	0.170	0.170	0.140	
Min, Max	0.01, 10.78	0.00, 38.21	0.00, 34.76	0.00, 23.14	
C4D1 CFB					
n	3	9	57	122	
LS Mean (StdErr) [2]	-0.01 (0.820)	-1.12 (0.725)	0.19 (0.283)	-0.93 (0.211)	
95% CI [2]	-1.90, 1.88	-2.79, 0.55	-0.37, 0.75	-1.35, -0.52	
Difference (95% CI) in CFB [2]		-1.11 (-3.28, 1.05)		-1.13 (-1.75, -0.50)	
p-value [3]		0.270		<0.001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-thpy-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.1.8a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	54	120	
Mean (StdDev)	3.210 (4.9238)	5.145 (13.1708)	2.249 (5.3758)	1.236 (3.2653)	
Median	1.175	0.085	0.185	0.140	
Min, Max	0.02, 10.47	0.01, 37.64	0.00, 26.39	0.00, 24.06	
C5D1 CFB					
n	4	8	54	120	
LS Mean (StdErr) [2]	-0.28 (0.823)	-1.21 (0.823)	0.28 (0.316)	-0.96 (0.232)	
95% CI [2]	-2.18, 1.62	-3.11, 0.69	-0.35, 0.90	-1.42, -0.51	
Difference (95% CI) in CFB [2]		-0.93 (-3.36, 1.50)		-1.24 (-1.95, -0.54)	
p-value [3]		0.403		<0.001	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-thpy-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.1.8a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	57	118	
Mean (StdDev)	3.418 (5.2118)	4.519 (12.2792)	3.666 (7.9386)	1.149 (3.2536)	
Median	1.270	0.140	0.240	0.120	
Min, Max	0.02, 11.11	0.00, 37.19	0.00, 38.37	0.00, 25.86	
C6D1 CFB					
n	4	9	57	118	
LS Mean (StdErr) [2]	-0.13 (0.863)	-1.48 (0.863)	0.17 (0.302)	-0.85 (0.226)	
95% CI [2]	-2.09, 1.82	-3.44, 0.47	-0.43, 0.76	-1.29, -0.40	
Difference (95% CI) in CFB [2]		-1.35 (-3.84, 1.14)		-1.01 (-1.68, -0.34)	
p-value [3]		0.251		0.003	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-thpy-a.sas Date: 15:43/07AUG2023

Table 35.2.4.1.1.8a
Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	9	58	123	
Mean (StdDev)	3.393 (5.2909)	4.671 (12.6133)	3.085 (6.7273)	1.312 (3.3111)	
Median	1.165	0.130	0.225	0.140	
Min, Max	0.03, 11.21	0.00, 38.22	0.00, 28.10	0.00, 24.80	
C7D1 CFB					
n	4	9	58	123	
LS Mean (StdErr) [2]	-0.17 (0.734)	-1.41 (0.734)	0.31 (0.334)	-0.98 (0.252)	
95% CI [2]	-1.83, 1.49	-3.07, 0.25	-0.35, 0.97	-1.48, -0.48	
Difference (95% CI) in CFB [2]		-1.24 (-3.36, 0.87)		-1.29 (-2.03, -0.54)	
Hedges'G (95% CI) in CFB		-0.57 (-2.05, 0.65)		-0.47 (-0.80, -0.16)	
p-value [3]		0.216		<0.001	
					0.937

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-sum-g-itt-thpy-a.sas Date: 15:43/07AUG2023

Table 35.2.4.3.1a
Summary of KIT D816V Mutation Allele Fraction in Blood at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1 with detectable mutation at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in KIT D816V MAF or undetectable (<0.02%) for patients with detectable mutation at Baseline	Placebo (N=63) n/N (%) (95% CIs)	Avapritinib 25 mg (N=118) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	4/ 63 (6.3) (1.8, 15.5)	80/118 (67.8) (58.6, 76.1)	39.34 (10.93, 140.56) <0.0001	11.18 (4.21, 29.65) <0.0001	0.63 (0.52, 0.73) <0.0001	
Age Group (Years)						0.943
< 65	4/ 52 (7.7) (2.1, 18.5)	71/109 (65.1) (55.4, 74.0)	26.77 (7.53, 97.61) <0.0001	8.52 (3.30, 22.02) <0.0001	0.58 (0.46, 0.70) <0.0001	
>= 65	0/ 11 (0.0) (0.0, 28.5)	9/ 9 (100.0) (66.4, 100.0)	NE (7.73, NE) <0.0001	NE (NE, NE) NE	1.00 (1.00, 1.00) NE	
Sex						0.047
Male	3/ 15 (20.0) (4.3, 48.1)	24/ 35 (68.6) (50.7, 83.1)	7.05 (1.31, 41.40) 0.008	3.10 (1.11, 8.66) 0.031	0.43 (0.16, 0.69) 0.002	
Female	1/ 48 (2.1) (0.1, 11.1)	56/ 83 (67.5) (56.3, 77.4)	176.56 (17.27, 5095.25) <0.0001	37.96 (4.75, 303.43) <0.001	0.68 (0.57, 0.79) <0.0001	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with detectable mutation at Baseline will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-resp-itt-a.sas Date: 14:56/14APR2023

Table 35.2.4.3.1a
Summary of KIT D816V Mutation Allele Fraction in Blood at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1 with detectable mutation at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in KIT D816V MAF or undetectable (<0.02%) for patients with detectable mutation at Baseline	Placebo (N=63) n/N (%) (95% CIs)	Avapritinib 25 mg (N=118) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Region						0.280
North America	3/ 29 (10.3) (2.2, 27.4)	32/ 48 (66.7) (51.6, 79.6)	20.41 (4.10, 109.17) <0.0001	6.45 (2.16, 19.31) <0.001	0.58 (0.39, 0.76) <0.0001	
Europe	1/ 34 (2.9) (0.1, 15.3)	48/ 70 (68.6) (56.4, 79.1)	97.06 (10.52, 3152.96) <0.0001	25.02 (3.38, 185.14) 0.002	0.66 (0.54, 0.78) <0.0001	
Country						>0.999
BEL	0/ 1 (0.0) (0.0, 97.5)	2/ 3 (66.7) (9.4, 99.2)	NE (NE, NE) NE	NE (NE, NE) NE	0.00 (0.00, 0.00) NE	
CAN	0/ 5 (0.0) (0.0, 52.2)	4/ 4 (100.0) (39.8, 100.0)	NE (0.21, NE) 0.046	NE (NE, NE) NE	1.00 (1.00, 1.00) NE	
CHE	0/ 1 (0.0) (0.0, 97.5)	0/ 1 (0.0) (0.0, 97.5)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DEU	1/ 13 (7.7) (0.2, 36.0)	13/ 19 (68.4) (43.4, 87.4)	33.22 (2.15, 976.53) 0.001	9.06 (1.30, 63.27) 0.026	0.60 (0.35, 0.85) <0.0001	
DNK	0/0	0/ 1 (0.0) (0.0, 97.5)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with detectable mutation at Baseline will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-resp-itt-a.sas Date: 14:56/14APR2023

Table 35.2.4.3.1a
Summary of KIT D816V Mutation Allele Fraction in Blood at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1 with detectable mutation at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in KIT D816V MAF or undetectable (<0.02%) for patients with detectable mutation at Baseline	Placebo (N=63) n/N (%) (95% CIs)	Avapritinib 25 mg (N=118) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
ESP	0/ 3 (0.0) (0.0, 70.8)	7/ 10 (70.0) (34.8, 93.3)	NE (0.80, NE) 0.039	NE (NE, NE) NE	0.85 (0.65, 1.00) <0.0001	
FRA	0/ 6 (0.0) (0.0, 45.9)	8/ 10 (80.0) (44.4, 97.5)	NE (2.12, NE) 0.006	NE (NE, NE) NE	0.81 (0.47, 1.00) <0.0001	
GBR	0/ 4 (0.0) (0.0, 60.2)	8/ 10 (80.0) (44.4, 97.5)	NE (2.17, NE) 0.008	NE (NE, NE) NE	0.85 (0.66, 1.00) <0.0001	
ITA	0/0	0/ 1 (0.0) (0.0, 97.5)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
NLD	0/ 2 (0.0) (0.0, 84.2)	5/ 9 (55.6) (21.2, 86.3)	NE (0.04, NE) 0.414	NE (NE, NE) NE	0.33 (-0.20, 0.87) 0.221	
NOR	0/ 3 (0.0) (0.0, 70.8)	3/ 4 (75.0) (19.4, 99.4)	NE (0.58, NE) 0.074	NE (NE, NE) NE	0.80 (0.45, 1.00) <0.0001	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with detectable mutation at Baseline will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-resp-itt-a.sas Date: 14:56/14APR2023

Table 35.2.4.3.1a
Summary of KIT D816V Mutation Allele Fraction in Blood at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1 with detectable mutation at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in KIT D816V MAF or undetectable (<0.02%) for patients with detectable mutation at Baseline	Placebo (N=63) n/N (%) (95% CIs)	Avapritinib 25 mg (N=118) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
SWE	0/ 1 (0.0) (0.0, 97.5)	2/ 2 (100.0) (15.8, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
USA	3/ 24 (12.5) (2.7, 32.4)	28/ 44 (63.6) (47.8, 77.6)	14.11 (2.75, 77.03) <0.0001	4.89 (1.71, 14.00) 0.003	0.51 (0.31, 0.72) <0.0001	
Baseline ISM Status						0.323
Moderate	3/ 23 (13.0) (2.8, 33.6)	31/ 42 (73.8) (58.0, 86.1)	20.43 (4.14, 121.89) <0.0001	5.86 (1.96, 17.49) 0.002	0.62 (0.42, 0.81) <0.0001	
Severe	1/ 40 (2.5) (0.1, 13.2)	49/ 74 (66.2) (54.3, 76.8)	80.48 (10.96, 3136.81) <0.0001	25.36 (3.73, 172.50) <0.001	0.63 (0.51, 0.75) <0.0001	
Baseline Serum Tryptase (ng/mL)						0.977
< 20	0/ 10 (0.0) (0.0, 30.8)	13/ 22 (59.1) (36.4, 79.3)	NE (2.17, NE) 0.005	NE (NE, NE) NE	0.53 (0.28, 0.78) <0.0001	
>= 20	4/ 53 (7.5) (2.1, 18.2)	67/ 96 (69.8) (59.6, 78.7)	34.40 (9.78, 130.75) <0.0001	9.86 (3.73, 26.08) <0.0001	0.64 (0.53, 0.76) <0.0001	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with detectable mutation at Baseline will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-resp-itt-a.sas Date: 14:56/14APR2023

Table 35.2.4.3.1a
Summary of KIT D816V Mutation Allele Fraction in Blood at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1 with detectable mutation at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in KIT D816V MAF or undetectable (<0.02%) for patients with detectable mutation at Baseline	Placebo (N=63) n/N (%) (95% CIs)	Avapritinib 25 mg (N=118) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.978
0 or 1	4/ 59 (6.8) (1.9, 16.5)	75/110 (68.2) (58.6, 76.7)	38.51 (10.39, 138.08) <0.0001	10.46 (3.97, 27.55) <0.0001	0.63 (0.52, 0.73) <0.0001	
2+	0/ 4 (0.0) (0.0, 60.2)	5/ 8 (62.5) (24.5, 91.5)	NE (0.63, NE) 0.069	NE (NE, NE) NE	0.60 (0.23, 0.97) 0.002	
Prior TKI therapy						0.976
Yes	0/ 4 (0.0) (0.0, 60.2)	4/ 6 (66.7) (22.3, 95.7)	NE (0.34, NE) 0.117	NE (NE, NE) NE	0.73 (0.40, 1.00) <0.0001	
No	4/ 59 (6.8) (1.9, 16.5)	76/112 (67.9) (58.4, 76.4)	36.31 (10.16, 132.53) <0.0001	10.23 (3.90, 26.83) <0.0001	0.62 (0.51, 0.73) <0.0001	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with detectable mutation at Baseline will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mut-resp-itt-a.sas Date: 14:56/14APR2023

Table 35.2.5.1.1.1a
Change from Baseline in Bone Marrow Mast Cells by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	60	132	11	9	
Mean (StdDev)	11.0 (12.11)	10.5 (10.33)	18.8 (13.83)	18.8 (18.20)	
Median	5.5	6.0	15.0	10.0	
Min, Max	1, 70	1, 50	3, 40	5, 50	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-sum-g-itt-age-a.sas Date: 15:44/07AUG2023

Table 35.2.5.1.1.1a
Change from Baseline in Bone Marrow Mast Cells by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	112	9	9	
Mean (StdDev)	9.7 (10.37)	7.0 (10.78)	14.1 (10.94)	9.1 (9.65)	
Median	6.0	3.5	10.0	5.0	
Min, Max	1, 60	1, 90	5, 40	2, 30	
C7D1 CFB					
n	52	112	9	9	
LS Mean (StdErr) [2]	-0.49 (1.322)	-1.88 (0.941)	-4.81 (6.051)	-8.97 (6.051)	
95% CI [2]	-3.10, 2.12	-3.74, -0.02	-17.70, 8.09	-21.87, 3.92	
Difference (95% CI) in CFB [2]		-1.39 (-4.32, 1.54)		-4.17 (-22.93, 14.60)	
Hedges'G (95% CI) in CFB		-0.14 (-0.47, 0.19)		-0.22 (-1.25, 0.75)	
p-value [3]		0.349		0.643	
					0.483

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-sum-g-itt-age-a.sas Date: 15:44/07AUG2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.2.5.1.1.2a
Change from Baseline in Bone Marrow Mast Cells by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	17	41	54	100	
Mean (StdDev)	15.6 (18.52)	12.7 (13.05)	11.1 (10.08)	10.4 (10.17)	
Median	10.0	7.0	7.0	6.0	
Min, Max	1, 70	1, 50	2, 40	1, 50	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-sum-g-itt-sex-a.sas Date: 15:44/07AUG2023

Table 35.2.5.1.1.2a
Change from Baseline in Bone Marrow Mast Cells by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	15	36	46	85	
Mean (StdDev)	14.1 (16.32)	8.8 (10.60)	9.1 (7.58)	6.5 (10.70)	
Median	7.0	5.0	7.0	4.0	
Min, Max	1, 60	1, 40	1, 40	1, 90	
C7D1 CFB					
n	15	36	46	85	
LS Mean (StdErr) [2]	-1.27 (2.827)	-2.89 (1.901)	-0.22 (1.621)	-1.57 (1.269)	
95% CI [2]	-6.96, 4.41	-6.72, 0.93	-3.43, 2.99	-4.08, 0.94	
Difference (95% CI) in CFB [2]		-1.62 (-7.96, 4.71)		-1.35 (-4.92, 2.22)	
Hedges'G (95% CI) in CFB		-0.14 (-0.77, 0.47)		-0.12 (-0.48, 0.24)	
p-value [3]		0.609		0.456	
					0.901

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-sum-g-itt-sex-a.sas Date: 15:44/07AUG2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.2.5.1.1.3a
Change from Baseline in Bone Marrow Mast Cells by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	33	60	38	81	
Mean (StdDev)	10.6 (8.59)	11.2 (11.44)	13.6 (15.25)	10.9 (10.89)	
Median	7.0	7.0	5.0	5.0	
Min, Max	2, 40	1, 50	1, 70	1, 50	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-sum-g-itt-reg-a.sas Date: 15:44/07AUG2023

Table 35.2.5.1.1.3a
Change from Baseline in Bone Marrow Mast Cells by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	26	53	35	68	
Mean (StdDev)	7.8 (5.06)	7.9 (13.71)	12.2 (12.90)	6.6 (7.59)	
Median	7.0	5.0	7.0	3.5	
Min, Max	1, 20	1, 90	1, 60	1, 40	
C7D1 CFB					
n	26	53	35	68	
LS Mean (StdErr) [2]	-1.72 (2.775)	-1.92 (2.140)	0.17 (1.340)	-2.35 (0.975)	
95% CI [2]	-7.25, 3.81	-6.19, 2.34	-2.49, 2.83	-4.28, -0.41	
Difference (95% CI) in CFB [2]		-0.21 (-6.38, 5.97)		-2.52 (-5.48, 0.45)	
Hedges'G (95% CI) in CFB		-0.01 (-0.49, 0.46)		-0.31 (-0.73, 0.10)	
p-value [3]		0.947		0.096	
					0.471

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-sum-g-itt-reg-a.sas Date: 15:44/07AUG2023

Table 35.2.5.1.1.4a
Change from Baseline in Bone Marrow Mast Cells by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-sum-g-itt-cou-a.sas Date: 15:44/07AUG2023

Table 35.2.5.1.1.4a
Change from Baseline in Bone Marrow Mast Cells by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-sum-g-itt-cou-a.sas Date: 15:44/07AUG2023

Table 35.2.5.1.1.4a
Change from Baseline in Bone Marrow Mast Cells by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-sum-g-itt-cou-a.sas Date: 15:44/07AUG2023

Table 35.2.5.1.1.4a
Change from Baseline in Bone Marrow Mast Cells by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-sum-g-itt-cou-a.sas Date: 15:44/07AUG2023

Table 35.2.5.1.1.4a
Change from Baseline in Bone Marrow Mast Cells by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-sum-g-itt-cou-a.sas Date: 15:44/07AUG2023

Table 35.2.5.1.1.5a
Change from Baseline in Bone Marrow Mast Cells by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	26	52	45	87	
Mean (StdDev)	13.8 (16.37)	11.8 (12.34)	11.3 (9.92)	10.4 (10.22)	
Median	8.5	6.0	7.0	7.0	
Min, Max	1, 70	1, 50	2, 40	1, 50	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-sum-g-itt-ism-a.sas Date: 15:45/07AUG2023

Table 35.2.5.1.1.5a
Change from Baseline in Bone Marrow Mast Cells by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	39	71	
Mean (StdDev)	13.6 (14.85)	8.8 (14.61)	8.5 (6.46)	6.0 (6.82)	
Median	8.5	4.5	5.0	3.0	
Min, Max	1, 60	1, 90	1, 30	1, 40	
C7D1 CFB					
n	22	48	39	71	
LS Mean (StdErr) [2]	0.76 (3.180)	-1.86 (2.200)	-1.90 (1.207)	-2.69 (0.944)	
95% CI [2]	-5.59, 7.10	-6.25, 2.53	-4.29, 0.50	-4.56, -0.82	
Difference (95% CI) in CFB [2]		-2.61 (-9.47, 4.25)		-0.79 (-3.57, 1.99)	
Hedges'G (95% CI) in CFB		-0.17 (-0.69, 0.34)		-0.10 (-0.50, 0.29)	
p-value [3]		0.450		0.573	
					0.555

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-sum-g-itt-ism-a.sas Date: 15:45/07AUG2023

Table 35.2.5.1.1.6a
Change from Baseline in Bone Marrow Mast Cells by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	15	28	56	113	
Mean (StdDev)	3.6 (1.24)	2.9 (2.16)	14.5 (13.28)	13.0 (11.49)	
Median	3.0	2.5	10.0	10.0	
Min, Max	2, 5	1, 10	1, 70	2, 50	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-sum-g-itt-tryp-a.sas Date: 15:45/07AUG2023

Table 35.2.5.1.1.6a
Change from Baseline in Bone Marrow Mast Cells by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	12	27	49	94	
Mean (StdDev)	3.4 (2.47)	2.7 (2.00)	12.0 (11.00)	8.5 (11.76)	
Median	3.0	2.0	10.0	5.0	
Min, Max	1, 10	1, 10	1, 60	1, 90	
C7D1 CFB					
n	12	27	49	94	
LS Mean (StdErr) [2]	-0.16 (0.644)	-0.26 (0.417)	-2.12 (1.598)	-3.93 (1.171)	
95% CI [2]	-1.47, 1.14	-1.11, 0.58	-5.28, 1.04	-6.25, -1.62	
Difference (95% CI) in CFB [2]		-0.10 (-1.62, 1.42)		-1.82 (-5.69, 2.06)	
Hedges'G (95% CI) in CFB		-0.04 (-0.75, 0.66)		-0.16 (-0.51, 0.19)	
p-value [3]		0.894		0.356	
					0.703

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-sum-g-itt-tryp-a.sas Date: 15:45/07AUG2023

Table 35.2.5.1.1.7a
Change from Baseline in Bone Marrow Mast Cells by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	67	131	4	10	
Mean (StdDev)	12.2 (12.84)	10.8 (10.87)	12.0 (9.27)	14.6 (13.78)	
Median	7.0	7.0	10.0	10.0	
Min, Max	1, 70	1, 50	3, 25	4, 50	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-sum-g-itt-ecog-a.sas Date: 15:45/07AUG2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.2.5.1.1.7a
Change from Baseline in Bone Marrow Mast Cells by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	113	3	8	
Mean (StdDev)	10.4 (10.74)	7.3 (10.94)	9.0 (1.73)	6.3 (6.18)	
Median	7.0	4.0	10.0	4.5	
Min, Max	1, 60	1, 90	7, 10	1, 20	
C7D1 CFB					
n	58	113	3	8	
LS Mean (StdErr) [2]	-0.48 (1.459)	-2.21 (1.094)	-5.80 (3.850)	-2.84 (2.780)	
95% CI [2]	-3.36, 2.40	-4.36, -0.05	-14.90, 3.31	-9.41, 3.73	
Difference (95% CI) in CFB [2]		-1.73 (-4.98, 1.52)		2.95 (-4.76, 10.67)	
Hedges'G (95% CI) in CFB		-0.15 (-0.47, 0.17)		0.35 (-1.09, 2.00)	
p-value [3]		0.295		0.395	
					0.542

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-sum-g-itt-ecog-a.sas Date: 15:45/07AUG2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.2.5.1.1.8a
Change from Baseline in Bone Marrow Mast Cells by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	67	131	
Mean (StdDev)	10.0 (5.77)	10.7 (11.40)	12.4 (12.92)	11.1 (11.11)	
Median	10.0	7.0	7.0	7.0	
Min, Max	5, 15	3, 40	1, 70	1, 50	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-sum-g-itt-thpy-a.sas Date: 15:45/07AUG2023

Table 35.2.5.1.1.8a
Change from Baseline in Bone Marrow Mast Cells by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	7	57	114	
Mean (StdDev)	8.8 (4.79)	8.0 (10.07)	10.5 (10.78)	7.1 (10.75)	
Median	7.5	3.0	7.0	4.0	
Min, Max	5, 15	2, 30	1, 60	1, 90	
C7D1 CFB					
n	4	7	57	114	
LS Mean (StdErr) [2]	-0.12 (3.821)	5.13 (3.821)	-0.68 (1.467)	-2.39 (1.088)	
95% CI [2]	-9.16, 8.91	-3.91, 14.16	-3.58, 2.21	-4.54, -0.24	
Difference (95% CI) in CFB [2]		5.25 (-6.36, 16.86)		-1.71 (-4.94, 1.52)	
Hedges'G (95% CI) in CFB		0.51 (-0.79, 2.11)		-0.15 (-0.47, 0.17)	
p-value [3]		0.320		0.297	
					0.563

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.6
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-sum-g-itt-thpy-a.sas Date: 15:45/07AUG2023

Table 35.2.5.2.1a
Summary of Bone Marrow Mast Cells at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1 with aggregates at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in Bone Marrow MCs or no aggregates for patients with aggregates at Baseline	Placebo (N=57) n/N (%) (95% CIs)	Avapritinib 25 mg (N=106) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	13/ 57 (22.8) (12.7, 35.8)	56/106 (52.8) (42.9, 62.6)	4.74 (2.06, 11.45) <0.0001	2.64 (1.53, 4.56) <0.001	0.34 (0.20, 0.48) <0.0001	
Age Group (Years)						0.996
< 65	10/ 47 (21.3) (10.7, 35.7)	50/ 97 (51.5) (41.2, 61.8)	5.41 (2.09, 15.52) <0.0001	2.89 (1.52, 5.48) 0.001	0.35 (0.20, 0.50) <0.0001	
>= 65	3/ 10 (30.0) (6.7, 65.2)	6/ 9 (66.7) (29.9, 92.5)	2.80 (0.24, 29.35) 0.317	1.60 (0.67, 3.84) 0.293	0.25 (-0.23, 0.73) 0.310	
Sex						0.195
Male	5/ 14 (35.7) (12.8, 64.9)	16/ 31 (51.6) (33.1, 69.8)	2.10 (0.43, 11.19) 0.311	1.45 (0.68, 3.09) 0.339	0.16 (-0.13, 0.45) 0.284	
Female	8/ 43 (18.6) (8.4, 33.4)	40/ 75 (53.3) (41.4, 64.9)	6.44 (2.26, 20.48) <0.0001	3.36 (1.62, 6.98) 0.001	0.38 (0.22, 0.54) <0.0001	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with aggregates at Baseline will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-resp-itt-a.sas Date: 14:56/14APR2023

Table 35.2.5.2.1a
Summary of Bone Marrow Mast Cells at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1 with aggregates at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in Bone Marrow MCs or no aggregates for patients with aggregates at Baseline	Placebo (N=57) n/N (%) (95% CIs)	Avapritinib 25 mg (N=106) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Region						0.196
North America	9/ 26 (34.6) (17.2, 55.7)	27/ 47 (57.4) (42.2, 71.7)	3.12 (0.95, 10.24) 0.037	1.79 (0.99, 3.23) 0.053	0.26 (0.03, 0.49) 0.024	
Europe	4/ 31 (12.9) (3.6, 29.8)	29/ 59 (49.2) (35.9, 62.5)	8.57 (2.11, 44.14) <0.001	4.87 (1.60, 14.85) 0.005	0.39 (0.23, 0.56) <0.0001	
Country						0.948
BEL	1/ 1 (100.0) (2.5, 100.0)	1/ 3 (33.3) (0.8, 90.6)	0.00 (0.00, 19.00) 0.317	0.00 (NE, NE) NE	-1.00 (-1.00, -1.00) NE	
CAN	1/ 5 (20.0) (0.5, 71.6)	6/ 8 (75.0) (34.9, 96.8)	NE (0.11, NE) 0.157	2.33 (0.34, 15.80) 0.385	0.32 (-0.17, 0.81) 0.199	
CHE	0/0	0/ 1 (0.0) (0.0, 97.5)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DEU	1/ 13 (7.7) (0.2, 36.0)	5/ 12 (41.7) (15.2, 72.3)	NE (1.31, NE) 0.022	NE (NE, NE) NE	0.41 (0.12, 0.69) 0.005	
DNK	0/0	0/ 1 (0.0) (0.0, 97.5)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with aggregates at Baseline will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-resp-itt-a.sas Date: 14:56/14APR2023

Table 35.2.5.2.1a
Summary of Bone Marrow Mast Cells at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1 with aggregates at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in Bone Marrow MCs or no aggregates for patients with aggregates at Baseline	Placebo (N=57) n/N (%) (95% CIs)	Avapritinib 25 mg (N=106) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
ESP	0/ 3 (0.0) (0.0, 70.8)	9/ 12 (75.0) (42.8, 94.5)	NE (0.89, NE) 0.034	NE (NE, NE) NE	0.75 (0.49, 1.00) <0.0001	
FRA	1/ 4 (25.0) (0.6, 80.6)	5/ 8 (62.5) (24.5, 91.5)	4.00 (0.03, 391.00) 0.462	1.60 (0.37, 6.85) 0.526	0.20 (-0.32, 0.72) 0.441	
GBR	1/ 5 (20.0) (0.5, 71.6)	3/ 8 (37.5) (8.5, 75.5)	0.93 (0.01, 78.44) 0.967	0.93 (0.03, 32.75) >0.999	-0.01 (-0.51, 0.49) 0.965	
ITA	0/0	0/ 1 (0.0) (0.0, 97.5)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
NLD	0/ 2 (0.0) (0.0, 84.2)	2/ 6 (33.3) (4.3, 77.7)	NE (0.04, NE) 0.414	NE (NE, NE) NE	0.33 (-0.20, 0.87) 0.221	
NOR	0/ 3 (0.0) (0.0, 70.8)	4/ 5 (80.0) (28.4, 99.5)	NE (0.65, NE) 0.055	NE (NE, NE) NE	0.79 (0.41, 1.00) <0.0001	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with aggregates at Baseline will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-resp-itt-a.sas Date: 14:56/14APR2023

Table 35.2.5.2.1a
Summary of Bone Marrow Mast Cells at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1 with aggregates at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in Bone Marrow MCs or no aggregates for patients with aggregates at Baseline	Placebo (N=57) n/N (%) (95% CIs)	Avapritinib 25 mg (N=106) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
SWE	0/0	0/ 2 (0.0) (0.0, 84.2)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
USA	8/ 21 (38.1) (18.1, 61.6)	21/ 39 (53.8) (37.2, 69.9)	2.12 (0.60, 7.51) 0.202	1.48 (0.80, 2.77) 0.215	0.18 (-0.08, 0.45) 0.178	
Baseline ISM Status						0.208
Moderate	2/ 19 (10.5) (1.3, 33.1)	23/ 42 (54.8) (38.7, 70.2)	9.63 (1.92, 94.88) 0.001	5.20 (1.35, 20.09) 0.017	0.44 (0.23, 0.65) <0.0001	
Severe	11/ 38 (28.9) (15.4, 45.9)	33/ 62 (53.2) (40.1, 66.0)	3.47 (1.27, 9.96) 0.007	2.05 (1.15, 3.68) 0.015	0.28 (0.09, 0.46) 0.003	
Baseline Serum Tryptase (ng/mL)						0.984
< 20	4/ 9 (44.4) (13.7, 78.8)	7/ 9 (77.8) (40.0, 97.2)	5.39 (0.45, 314.69) 0.120	2.10 (0.71, 6.17) 0.178	0.40 (-0.03, 0.84) 0.069	
>= 20	9/ 48 (18.8) (8.9, 32.6)	49/ 97 (50.5) (40.2, 60.8)	4.66 (1.91, 11.92) <0.001	2.77 (1.48, 5.17) 0.001	0.33 (0.18, 0.48) <0.0001	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with aggregates at Baseline will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-resp-itt-a.sas Date: 14:56/14APR2023

Table 35.2.5.2.1a
Summary of Bone Marrow Mast Cells at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1 with aggregates at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 50% Reductions in Bone Marrow MCs or no aggregates for patients with aggregates at Baseline	Placebo (N=57) n/N (%) (95% CIs)	Avapritinib 25 mg (N=106) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.328
0 or 1	12/ 54 (22.2) (12.0, 35.6)	53/ 98 (54.1) (43.7, 64.2)	5.31 (2.21, 13.42) <0.0001	2.80 (1.58, 4.96) <0.001	0.36 (0.21, 0.50) <0.0001	
2+	1/ 3 (33.3) (0.8, 90.6)	3/ 8 (37.5) (8.5, 75.5)	1.13 (0.04, 78.55) 0.926	1.10 (0.14, 8.92) 0.929	0.03 (-0.66, 0.73) 0.927	
Prior TKI therapy						0.564
Yes	1/ 3 (33.3) (0.8, 90.6)	4/ 9 (44.4) (13.7, 78.8)	NE (0.03, NE) 0.439	1.75 (0.32, 9.55) 0.518	0.20 (-0.15, 0.55) 0.264	
No	12/ 54 (22.2) (12.0, 35.6)	52/ 97 (53.6) (43.2, 63.8)	4.77 (2.03, 11.59) <0.0001	2.70 (1.52, 4.78) <0.001	0.35 (0.20, 0.49) <0.0001	

Abbreviations: CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with aggregates at Baseline will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-bm-resp-itt-a.sas Date: 14:56/14APR2023

Table 35.2.9.2.1.1a
Change from Baseline of EQ-5D-5L VAS by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	56	126	11	9	
Mean (StdDev)	53.3 (17.89)	57.2 (17.71)	69.4 (10.27)	57.6 (17.16)	
Median	56.0	59.5	70.0	60.0	
Min, Max	15, 91	15, 93	54, 94	40, 88	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-age-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.1a
Change from Baseline of EQ-5D-5L VAS by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	57	128	11	9	
Mean (StdDev)	55.6 (17.14)	59.6 (17.98)	67.5 (10.40)	62.1 (19.40)	
Median	60.0	60.0	70.0	65.0	
Min, Max	10, 81	20, 90	50, 80	30, 90	
C2D1 CFB					
n	54	123	11	9	
LS Mean (StdErr) [2]	1.72 (2.019)	1.98 (1.432)	-1.87 (6.836)	4.57 (8.670)	
95% CI [2]	-2.27, 5.70	-0.85, 4.81	-16.36, 12.63	-13.81, 22.95	
Difference (95% CI) in CFB [2]		0.26 (-4.06, 4.59)		6.44 (-7.07, 19.95)	
p-value [3]		0.905		0.327	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-age-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.1a
Change from Baseline of EQ-5D-5L VAS by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	119	10	9	
Mean (StdDev)	56.3 (18.91)	63.5 (18.09)	67.2 (20.25)	69.1 (15.35)	
Median	61.0	68.0	69.5	70.0	
Min, Max	12, 85	14, 96	17, 90	44, 85	
C3D1 CFB					
n	53	116	10	9	
LS Mean (StdErr) [2]	2.62 (2.326)	6.93 (1.636)	-1.53 (8.046)	11.31 (10.131)	
95% CI [2]	-1.97, 7.21	3.70, 10.16	-18.68, 15.62	-10.29, 32.90	
Difference (95% CI) in CFB [2]		4.31 (-0.70, 9.31)		12.83 (-3.24, 28.90)	
p-value [3]		0.091		0.109	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-age-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.1a
Change from Baseline of EQ-5D-5L VAS by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	53.6 (17.84)	63.5 (18.53)	66.9 (17.12)	71.6 (12.90)	
Median	54.0	65.0	61.0	74.0	
Min, Max	19, 90	10, 95	39, 91	50, 89	
C4D1 CFB					
n	49	116	7	9	
LS Mean (StdErr) [2]	1.10 (2.604)	6.60 (1.815)	-0.50 (8.719)	18.83 (11.626)	
95% CI [2]	-4.04, 6.25	3.01, 10.18	-19.50, 18.50	-6.50, 44.16	
Difference (95% CI) in CFB [2]		5.49 (0.02, 10.97)		19.33 (-1.86, 40.53)	
p-value [3]		0.049		0.070	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-age-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.1a
Change from Baseline of EQ-5D-5L VAS by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	117	9	8	
Mean (StdDev)	55.6 (18.98)	61.9 (18.54)	63.8 (11.98)	69.1 (14.22)	
Median	60.0	65.0	62.0	67.5	
Min, Max	10, 90	19, 93	41, 80	45, 91	
C5D1 CFB					
n	52	111	9	8	
LS Mean (StdErr) [2]	2.20 (2.548)	4.54 (1.826)	-3.20 (8.878)	10.65 (11.507)	
95% CI [2]	-2.84, 7.23	0.93, 8.15	-22.38, 15.98	-14.21, 35.51	
Difference (95% CI) in CFB [2]		2.34 (-3.10, 7.79)		13.85 (-5.52, 33.22)	
p-value [3]		0.397		0.147	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-age-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.1a
Change from Baseline of EQ-5D-5L VAS by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	52.8 (18.62)	63.5 (19.05)	64.1 (19.36)	68.3 (10.69)	
Median	53.5	68.5	63.0	71.0	
Min, Max	15, 91	13, 97	32, 96	50, 80	
C6D1 CFB					
n	51	114	8	9	
LS Mean (StdErr) [2]	0.20 (2.490)	5.82 (1.743)	-3.38 (8.699)	13.25 (11.709)	
95% CI [2]	-4.72, 5.12	2.38, 9.27	-22.18, 15.41	-12.05, 38.55	
Difference (95% CI) in CFB [2]		5.62 (0.29, 10.95)		16.63 (-4.10, 37.37)	
p-value [3]		0.039		0.107	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-age-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.1a
Change from Baseline of EQ-5D-5L VAS by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	54.2 (20.27)	63.7 (19.20)	66.0 (15.11)	65.5 (9.84)	
Median	54.0	67.0	62.0	66.0	
Min, Max	16, 93	5, 95	50, 97	50, 80	
C7D1 CFB					
n	49	113	10	8	
LS Mean (StdErr) [2]	0.94 (2.858)	5.84 (1.984)	-4.81 (7.940)	11.17 (10.504)	
95% CI [2]	-4.71, 6.58	1.92, 9.76	-21.84, 12.22	-11.36, 33.70	
Difference (95% CI) in CFB [2]		4.90 (-1.13, 10.94)		15.98 (-1.05, 33.01)	
Hedges'G (95% CI) in CFB		0.23 (-0.10, 0.58)		0.56 (-0.39, 1.67)	
p-value [3]		0.111		0.064	
					0.187

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-age-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.2a
Change from Baseline of EQ-5D-5L VAS by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	51	98	
Mean (StdDev)	51.6 (20.12)	59.9 (18.25)	57.3 (17.08)	56.2 (17.35)	
Median	52.5	60.0	60.0	58.0	
Min, Max	15, 80	20, 93	19, 94	15, 93	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-sex-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.2a
Change from Baseline of EQ-5D-5L VAS by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	15	39	53	98	
Mean (StdDev)	52.1 (16.35)	64.3 (17.57)	59.1 (16.71)	58.0 (17.95)	
Median	60.0	70.0	65.0	60.0	
Min, Max	15, 72	20, 90	10, 81	20, 90	
C2D1 CFB					
n	15	36	50	96	
LS Mean (StdErr) [2]	0.34 (3.813)	3.40 (2.565)	1.66 (2.120)	1.89 (1.683)	
95% CI [2]	-7.33, 8.02	-1.76, 8.56	-2.54, 5.85	-1.44, 5.21	
Difference (95% CI) in CFB [2]		3.05 (-5.48, 11.59)		0.23 (-4.26, 4.73)	
p-value [3]		0.475		0.919	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-sex-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.2a
Change from Baseline of EQ-5D-5L VAS by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	94	
Mean (StdDev)	51.5 (22.96)	68.4 (14.75)	60.1 (17.71)	62.3 (18.74)	
Median	58.0	70.0	64.5	65.0	
Min, Max	12, 84	30, 95	15, 90	14, 96	
C3D1 CFB					
n	16	33	47	92	
LS Mean (StdErr) [2]	-1.63 (4.036)	10.18 (2.897)	1.88 (2.569)	5.62 (1.967)	
95% CI [2]	-9.75, 6.50	4.35, 16.01	-3.20, 6.96	1.73, 9.51	
Difference (95% CI) in CFB [2]		11.81 (2.67, 20.94)		3.74 (-1.70, 9.18)	
p-value [3]		0.012		0.176	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-sex-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.2a
Change from Baseline of EQ-5D-5L VAS by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	48.2 (17.48)	68.3 (15.33)	57.5 (17.94)	62.5 (19.11)	
Median	44.0	70.5	60.0	64.0	
Min, Max	22, 80	25, 95	19, 91	10, 95	
C4D1 CFB					
n	14	34	42	91	
LS Mean (StdErr) [2]	-3.33 (3.898)	8.79 (2.735)	1.39 (3.040)	6.33 (2.280)	
95% CI [2]	-11.19, 4.53	3.28, 14.30	-4.62, 7.41	1.82, 10.84	
Difference (95% CI) in CFB [2]		12.12 (3.40, 20.84)		4.93 (-1.38, 11.24)	
p-value [3]		0.008		0.124	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-sex-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.2a
Change from Baseline of EQ-5D-5L VAS by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	89	
Mean (StdDev)	53.1 (19.89)	66.5 (15.43)	58.1 (17.73)	60.7 (19.21)	
Median	59.0	70.0	60.0	65.0	
Min, Max	18, 90	30, 90	10, 90	19, 93	
C5D1 CFB					
n	16	32	45	87	
LS Mean (StdErr) [2]	-0.41 (3.713)	5.62 (2.753)	0.95 (2.986)	4.40 (2.296)	
95% CI [2]	-7.89, 7.07	0.07, 11.17	-4.96, 6.86	-0.15, 8.94	
Difference (95% CI) in CFB [2]		6.03 (-2.32, 14.38)		3.45 (-2.91, 9.81)	
p-value [3]		0.152		0.285	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-sex-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.2a
Change from Baseline of EQ-5D-5L VAS by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	46.7 (17.92)	68.4 (15.01)	56.7 (18.79)	61.9 (19.67)	
Median	45.0	70.0	58.0	65.0	
Min, Max	16, 75	25, 97	15, 96	13, 95	
C6D1 CFB					
n	14	34	45	89	
LS Mean (StdErr) [2]	-4.85 (3.796)	7.77 (2.584)	0.44 (2.851)	5.53 (2.184)	
95% CI [2]	-12.51, 2.80	2.57, 12.98	-5.20, 6.08	1.21, 9.85	
Difference (95% CI) in CFB [2]		12.63 (4.11, 21.15)		5.09 (-0.99, 11.17)	
p-value [3]		0.005		0.100	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-sex-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.2a
Change from Baseline of EQ-5D-5L VAS by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	48.7 (22.38)	67.3 (12.06)	58.7 (18.55)	62.3 (20.82)	
Median	44.5	70.0	58.5	63.0	
Min, Max	16, 86	26, 91	17, 97	5, 95	
C7D1 CFB					
n	15	34	44	87	
LS Mean (StdErr) [2]	-5.20 (4.165)	8.91 (2.903)	1.55 (3.214)	5.11 (2.457)	
95% CI [2]	-13.59, 3.19	3.06, 14.75	-4.81, 7.91	0.25, 9.98	
Difference (95% CI) in CFB [2]		14.11 (4.78, 23.43)		3.56 (-3.14, 10.26)	
Hedges'G (95% CI) in CFB		0.83 (0.22, 1.52)		0.16 (-0.21, 0.53)	
p-value [3]		0.004		0.295	
					0.103

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-sex-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.3a
Change from Baseline of EQ-5D-5L VAS by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	37	80	
Mean (StdDev)	62.1 (14.76)	62.3 (16.51)	50.9 (18.73)	53.7 (17.57)	
Median	65.0	67.0	55.0	52.5	
Min, Max	30, 91	30, 93	15, 94	15, 90	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-reg-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.3a
Change from Baseline of EQ-5D-5L VAS by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	30	59	38	78	
Mean (StdDev)	61.7 (15.05)	65.0 (16.37)	54.2 (17.50)	55.8 (18.30)	
Median	66.5	70.0	59.0	55.0	
Min, Max	25, 81	20, 90	10, 80	20, 90	
C2D1 CFB					
n	28	54	37	78	
LS Mean (StdErr) [2]	-1.45 (2.877)	1.63 (2.251)	2.99 (2.415)	2.41 (1.789)	
95% CI [2]	-7.18, 4.28	-2.85, 6.11	-1.79, 7.78	-1.13, 5.96	
Difference (95% CI) in CFB [2]		3.08 (-3.20, 9.36)		-0.58 (-5.79, 4.63)	
p-value [3]		0.332		0.825	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-reg-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.3a
Change from Baseline of EQ-5D-5L VAS by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	52	37	76	
Mean (StdDev)	64.0 (15.91)	65.8 (17.76)	52.9 (20.65)	62.6 (18.02)	
Median	69.5	69.5	60.0	66.0	
Min, Max	20, 85	25, 91	12, 90	14, 96	
C3D1 CFB					
n	27	49	36	76	
LS Mean (StdErr) [2]	1.51 (3.449)	4.57 (2.725)	0.95 (2.763)	8.54 (1.999)	
95% CI [2]	-5.37, 8.39	-0.86, 10.00	-4.53, 6.43	4.58, 12.50	
Difference (95% CI) in CFB [2]		3.06 (-4.51, 10.63)		7.59 (1.62, 13.57)	
p-value [3]		0.423		0.013	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-reg-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.3a
Change from Baseline of EQ-5D-5L VAS by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	60.9 (18.94)	69.0 (15.76)	51.6 (16.90)	60.8 (19.18)	
Median	62.0	71.0	51.0	61.0	
Min, Max	22, 90	10, 91	19, 91	11, 95	
C4D1 CFB					
n	20	49	36	76	
LS Mean (StdErr) [2]	0.40 (3.726)	8.04 (2.775)	0.48 (3.118)	6.80 (2.276)	
95% CI [2]	-7.05, 7.84	2.50, 13.58	-5.70, 6.67	2.28, 11.31	
Difference (95% CI) in CFB [2]		7.64 (-0.05, 15.34)		6.31 (-0.44, 13.06)	
p-value [3]		0.052		0.066	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-reg-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.3a
Change from Baseline of EQ-5D-5L VAS by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	37	78	
Mean (StdDev)	61.1 (20.37)	67.2 (14.90)	53.6 (16.20)	59.4 (19.63)	
Median	64.0	70.0	55.0	63.5	
Min, Max	10, 90	31, 90	16, 80	19, 93	
C5D1 CFB					
n	25	42	36	77	
LS Mean (StdErr) [2]	-1.22 (3.471)	4.50 (2.839)	1.77 (3.213)	4.65 (2.332)	
95% CI [2]	-8.16, 5.72	-1.18, 10.18	-4.60, 8.14	0.03, 9.28	
Difference (95% CI) in CFB [2]		5.72 (-1.87, 13.31)		2.88 (-4.05, 9.82)	
p-value [3]		0.137		0.412	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-reg-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.3a
Change from Baseline of EQ-5D-5L VAS by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	57.6 (19.79)	69.5 (14.25)	52.1 (18.28)	60.0 (20.24)	
Median	61.0	70.5	50.0	63.0	
Min, Max	15, 91	40, 91	20, 96	13, 97	
C6D1 CFB					
n	23	47	36	76	
LS Mean (StdErr) [2]	-4.36 (3.400)	6.45 (2.604)	1.63 (3.027)	5.83 (2.190)	
95% CI [2]	-11.15, 2.43	1.25, 11.65	-4.37, 7.63	1.49, 10.17	
Difference (95% CI) in CFB [2]		10.81 (3.39, 18.23)		4.20 (-2.35, 10.75)	
p-value [3]		0.005		0.206	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-reg-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.3a
Change from Baseline of EQ-5D-5L VAS by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	63.6 (19.89)	70.0 (15.02)	51.0 (18.50)	59.8 (19.87)	
Median	66.0	74.5	50.0	61.0	
Min, Max	16, 93	30, 91	17, 97	5, 95	
C7D1 CFB					
n	23	45	36	76	
LS Mean (StdErr) [2]	-2.03 (3.657)	6.87 (2.860)	0.88 (3.485)	5.69 (2.521)	
95% CI [2]	-9.34, 5.28	1.16, 12.59	-6.03, 7.79	0.69, 10.68	
Difference (95% CI) in CFB [2]		8.90 (1.30, 16.50)		4.81 (-2.73, 12.34)	
Hedges'G (95% CI) in CFB		0.47 (-0.03, 1.01)		0.22 (-0.18, 0.63)	
p-value [3]		0.022		0.209	
					0.533

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-reg-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.4a
Change from Baseline of EQ-5D-5L VAS by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-cou-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.4a
Change from Baseline of EQ-5D-5L VAS by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-cou-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.4a
Change from Baseline of EQ-5D-5L VAS by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-cou-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.4a
Change from Baseline of EQ-5D-5L VAS by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-cou-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.4a
Change from Baseline of EQ-5D-5L VAS by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-cou-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.5a
Change from Baseline of EQ-5D-5L VAS by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	23	49	44	85	
Mean (StdDev)	61.5 (18.80)	63.8 (16.98)	53.0 (16.83)	53.5 (17.03)	
Median	68.0	68.0	55.0	50.0	
Min, Max	19, 94	20, 93	15, 90	15, 93	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-ism-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.5a
Change from Baseline of EQ-5D-5L VAS by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	24	50	44	85	
Mean (StdDev)	61.1 (16.32)	65.7 (16.90)	55.6 (16.87)	56.2 (17.99)	
Median	62.0	70.0	60.0	60.0	
Min, Max	10, 81	30, 90	15, 78	20, 90	
C2D1 CFB					
n	22	48	43	83	
LS Mean (StdErr) [2]	0.90 (3.262)	2.63 (2.126)	2.07 (2.194)	2.14 (1.770)	
95% CI [2]	-5.61, 7.41	-1.61, 6.88	-2.27, 6.41	-1.36, 5.65	
Difference (95% CI) in CFB [2]		1.73 (-4.90, 8.36)		0.07 (-4.99, 5.14)	
p-value [3]		0.604		0.977	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-ism-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.5a
Change from Baseline of EQ-5D-5L VAS by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	78	
Mean (StdDev)	60.7 (20.58)	70.4 (15.47)	56.5 (18.82)	59.9 (18.46)	
Median	64.5	70.0	60.0	63.0	
Min, Max	15, 90	25, 95	12, 85	14, 96	
C3D1 CFB					
n	19	47	44	77	
LS Mean (StdErr) [2]	1.06 (4.031)	8.64 (2.516)	2.20 (2.441)	6.45 (2.014)	
95% CI [2]	-7.00, 9.11	3.61, 13.67	-2.63, 7.04	2.46, 10.44	
Difference (95% CI) in CFB [2]		7.58 (-0.66, 15.82)		4.24 (-1.45, 9.94)	
p-value [3]		0.071		0.143	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-ism-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.5a
Change from Baseline of EQ-5D-5L VAS by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	61.8 (17.32)	71.4 (13.40)	51.6 (17.75)	59.9 (19.59)	
Median	60.0	73.5	50.0	64.0	
Min, Max	26, 91	40, 95	19, 90	10, 91	
C4D1 CFB					
n	18	44	38	80	
LS Mean (StdErr) [2]	-0.63 (3.774)	8.69 (2.444)	0.50 (3.021)	5.83 (2.317)	
95% CI [2]	-8.18, 6.93	3.80, 13.58	-5.49, 6.48	1.24, 10.42	
Difference (95% CI) in CFB [2]		9.31 (1.71, 16.92)		5.34 (-1.49, 12.16)	
p-value [3]		0.017		0.124	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-ism-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.5a
Change from Baseline of EQ-5D-5L VAS by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	41	78	
Mean (StdDev)	60.8 (14.21)	67.8 (14.99)	54.5 (20.06)	59.0 (19.56)	
Median	62.0	70.0	59.0	63.0	
Min, Max	25, 81	40, 90	10, 90	19, 93	
C5D1 CFB					
n	20	42	41	76	
LS Mean (StdErr) [2]	-0.80 (4.267)	4.97 (2.868)	1.54 (2.812)	4.71 (2.226)	
95% CI [2]	-9.34, 7.74	-0.77, 10.71	-4.03, 7.11	0.31, 9.12	
Difference (95% CI) in CFB [2]		5.77 (-2.88, 14.42)		3.17 (-3.32, 9.67)	
p-value [3]		0.187		0.335	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-ism-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.5a
Change from Baseline of EQ-5D-5L VAS by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	59.7 (18.00)	70.1 (14.09)	51.1 (18.97)	59.7 (20.07)	
Median	61.0	70.0	50.0	65.0	
Min, Max	22, 96	40, 97	15, 91	13, 95	
C6D1 CFB					
n	20	45	39	77	
LS Mean (StdErr) [2]	-4.06 (3.750)	6.04 (2.443)	0.18 (2.869)	5.86 (2.228)	
95% CI [2]	-11.56, 3.44	1.16, 10.93	-5.51, 5.86	1.45, 10.27	
Difference (95% CI) in CFB [2]		10.10 (2.48, 17.72)		5.68 (-0.93, 12.30)	
p-value [3]		0.010		0.092	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-ism-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.5a
Change from Baseline of EQ-5D-5L VAS by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	61.9 (18.60)	68.5 (14.90)	52.9 (20.12)	60.6 (20.42)	
Median	59.5	70.0	50.5	65.0	
Min, Max	30, 97	30, 91	16, 93	5, 95	
C7D1 CFB					
n	19	45	40	75	
LS Mean (StdErr) [2]	-0.68 (4.487)	5.98 (2.946)	-0.19 (3.095)	6.11 (2.444)	
95% CI [2]	-9.65, 8.30	0.09, 11.87	-6.32, 5.94	1.26, 10.95	
Difference (95% CI) in CFB [2]		6.65 (-2.34, 15.65)		6.30 (-0.76, 13.35)	
Hedges'G (95% CI) in CFB		0.33 (-0.20, 0.90)		0.30 (-0.08, 0.70)	
p-value [3]		0.144		0.080	
					0.958

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-ism-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.6a
Change from Baseline of EQ-5D-5L VAS by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	12	27	55	108	
Mean (StdDev)	62.1 (14.43)	55.1 (19.57)	54.6 (18.35)	57.8 (17.14)	
Median	61.0	60.0	59.0	58.5	
Min, Max	40, 90	20, 81	15, 94	15, 93	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-tryp-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.6a
Change from Baseline of EQ-5D-5L VAS by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	14	27	54	110	
Mean (StdDev)	59.4 (16.23)	60.7 (20.64)	57.1 (17.02)	59.5 (17.40)	
Median	64.5	65.0	60.0	60.0	
Min, Max	20, 75	25, 90	10, 81	20, 90	
C2D1 CFB					
n	12	26	53	106	
LS Mean (StdErr) [2]	-4.29 (3.477)	4.68 (2.104)	2.67 (1.883)	1.59 (1.369)	
95% CI [2]	-11.35, 2.77	0.41, 8.95	-1.05, 6.40	-1.12, 4.29	
Difference (95% CI) in CFB [2]		8.97 (0.97, 16.97)		-1.09 (-5.62, 3.44)	
p-value [3]		0.029		0.636	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-tryp-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.6a
Change from Baseline of EQ-5D-5L VAS by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	102	
Mean (StdDev)	61.7 (15.28)	62.5 (17.80)	56.8 (20.38)	64.3 (18.01)	
Median	66.0	69.0	61.0	68.0	
Min, Max	30, 85	30, 90	12, 90	14, 96	
C3D1 CFB					
n	12	26	51	99	
LS Mean (StdErr) [2]	-0.50 (4.684)	8.50 (2.835)	2.68 (2.168)	7.18 (1.577)	
95% CI [2]	-10.01, 9.01	2.74, 14.26	-1.60, 6.97	4.06, 10.30	
Difference (95% CI) in CFB [2]		9.00 (-1.78, 19.78)		4.50 (-0.70, 9.70)	
p-value [3]		0.099		0.089	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-tryp-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.6a
Change from Baseline of EQ-5D-5L VAS by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	57.8 (19.25)	60.1 (17.63)	54.4 (17.96)	65.0 (18.38)	
Median	60.0	62.0	56.0	67.0	
Min, Max	19, 90	25, 95	22, 91	10, 95	
C4D1 CFB					
n	10	24	46	101	
LS Mean (StdErr) [2]	-4.14 (6.927)	7.80 (4.121)	1.97 (2.283)	7.50 (1.582)	
95% CI [2]	-18.27, 9.98	-0.61, 16.20	-2.54, 6.49	4.37, 10.63	
Difference (95% CI) in CFB [2]		11.94 (-3.73, 27.62)		5.53 (0.13, 10.92)	
p-value [3]		0.130		0.045	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-tryp-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.6a
Change from Baseline of EQ-5D-5L VAS by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	99	
Mean (StdDev)	61.5 (19.39)	59.7 (17.95)	55.4 (17.97)	63.0 (18.46)	
Median	66.5	62.5	60.0	66.0	
Min, Max	16, 90	30, 90	10, 90	19, 93	
C5D1 CFB					
n	11	25	50	94	
LS Mean (StdErr) [2]	-1.82 (4.822)	5.20 (2.934)	1.50 (2.424)	4.88 (1.810)	
95% CI [2]	-11.63, 7.99	-0.77, 11.17	-3.29, 6.30	1.30, 8.46	
Difference (95% CI) in CFB [2]		7.02 (-3.83, 17.86)		3.37 (-2.51, 9.26)	
p-value [3]		0.197		0.259	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-tryp-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.6a
Change from Baseline of EQ-5D-5L VAS by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	62.2 (16.08)	61.6 (18.64)	52.0 (19.23)	64.4 (18.64)	
Median	61.0	60.0	51.0	70.0	
Min, Max	33, 91	25, 95	15, 96	13, 97	
C6D1 CFB					
n	11	26	48	97	
LS Mean (StdErr) [2]	-2.82 (4.679)	5.97 (2.776)	-0.75 (2.391)	6.08 (1.721)	
95% CI [2]	-12.33, 6.69	0.33, 11.62	-5.47, 3.98	2.68, 9.48	
Difference (95% CI) in CFB [2]		8.79 (-1.77, 19.36)		6.83 (1.08, 12.57)	
p-value [3]		0.100		0.020	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-tryp-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.6a
Change from Baseline of EQ-5D-5L VAS by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	61.7 (18.18)	61.2 (17.12)	54.6 (20.26)	64.5 (19.13)	
Median	68.0	61.0	55.0	68.5	
Min, Max	28, 93	26, 90	16, 97	5, 95	
C7D1 CFB					
n	10	24	49	97	
LS Mean (StdErr) [2]	-4.35 (6.138)	6.38 (3.651)	0.88 (2.529)	6.43 (1.823)	
95% CI [2]	-16.86, 8.17	-1.07, 13.83	-4.12, 5.88	2.82, 10.03	
Difference (95% CI) in CFB [2]		10.73 (-3.16, 24.62)		5.55 (-0.52, 11.62)	
Hedges'G (95% CI) in CFB		0.57 (-0.17, 1.39)		0.31 (-0.03, 0.66)	
p-value [3]		0.125		0.073	
					0.510

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-tryp-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.7a
Change from Baseline of EQ-5D-5L VAS by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	63	125	4	10	
Mean (StdDev)	57.9 (16.42)	57.5 (17.78)	24.5 (6.35)	53.6 (15.61)	
Median	60.0	60.0	24.5	54.5	
Min, Max	15, 94	15, 93	19, 30	32, 80	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-ecog-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.7a
Change from Baseline of EQ-5D-5L VAS by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	64	128	4	9	
Mean (StdDev)	59.2 (15.54)	60.4 (17.94)	31.3 (15.17)	50.7 (17.41)	
Median	62.0	61.5	35.5	50.0	
Min, Max	15, 81	20, 90	10, 44	20, 71	
C2D1 CFB					
n	61	123	4	9	
LS Mean (StdErr) [2]	0.67 (1.894)	2.21 (1.433)	11.54 (9.878)	3.49 (7.523)	
95% CI [2]	-3.07, 4.40	-0.61, 5.04	-10.80, 33.89	-13.53, 20.51	
Difference (95% CI) in CFB [2]		1.55 (-2.57, 5.66)		-8.05 (-26.75, 10.64)	
p-value [3]		0.459		0.355	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-ecog-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.7a
Change from Baseline of EQ-5D-5L VAS by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	119	4	9	
Mean (StdDev)	58.9 (18.78)	64.5 (18.05)	41.8 (24.20)	56.1 (14.71)	
Median	62.0	69.0	41.0	60.0	
Min, Max	12, 90	14, 96	15, 70	40, 74	
C3D1 CFB					
n	59	116	4	9	
LS Mean (StdErr) [2]	0.30 (2.164)	7.33 (1.617)	17.91 (13.846)	4.77 (10.545)	
95% CI [2]	-3.97, 4.57	4.14, 10.52	-13.41, 49.23	-19.08, 28.63	
Difference (95% CI) in CFB [2]		7.03 (2.32, 11.75)		-13.14 (-39.35, 13.06)	
p-value [3]		0.004		0.286	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-ecog-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.7a
Change from Baseline of EQ-5D-5L VAS by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	56.6 (17.64)	65.1 (18.32)	34.8 (12.95)	51.9 (13.04)	
Median	60.0	67.0	29.5	52.5	
Min, Max	19, 91	10, 95	26, 54	30, 74	
C4D1 CFB					
n	52	115	4	10	
LS Mean (StdErr) [2]	-0.76 (2.450)	7.60 (1.790)	12.96 (14.291)	1.26 (10.942)	
95% CI [2]	-5.60, 4.08	4.06, 11.13	-18.88, 44.81	-23.12, 25.64	
Difference (95% CI) in CFB [2]		8.36 (3.12, 13.60)		-11.70 (-38.15, 14.74)	
p-value [3]		0.002		0.347	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-ecog-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.7a
Change from Baseline of EQ-5D-5L VAS by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	115	4	10	
Mean (StdDev)	58.4 (17.67)	63.4 (18.23)	32.8 (8.58)	50.2 (15.60)	
Median	60.0	66.0	30.5	47.5	
Min, Max	10, 90	19, 93	25, 45	21, 70	
C5D1 CFB					
n	57	109	4	10	
LS Mean (StdErr) [2]	-0.25 (2.431)	5.23 (1.846)	13.81 (12.263)	0.80 (9.389)	
95% CI [2]	-5.05, 4.55	1.59, 8.88	-13.51, 41.14	-20.12, 21.72	
Difference (95% CI) in CFB [2]		5.49 (0.19, 10.78)		-13.02 (-35.71, 9.67)	
p-value [3]		0.042		0.230	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-ecog-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.7a
Change from Baseline of EQ-5D-5L VAS by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	56.0 (18.28)	65.1 (18.24)	29.3 (7.27)	48.6 (16.78)	
Median	58.0	70.0	28.0	48.0	
Min, Max	15, 96	13, 97	22, 39	20, 70	
C6D1 CFB					
n	55	113	4	10	
LS Mean (StdErr) [2]	-1.79 (2.295)	6.73 (1.694)	8.61 (14.995)	0.72 (11.481)	
95% CI [2]	-6.32, 2.74	3.38, 10.07	-24.80, 42.02	-24.86, 26.30	
Difference (95% CI) in CFB [2]		8.52 (3.52, 13.52)		-7.89 (-35.63, 19.86)	
p-value [3]		<0.001		0.541	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-ecog-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.7a
Change from Baseline of EQ-5D-5L VAS by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	57.8 (19.46)	65.2 (18.64)	31.5 (1.29)	48.0 (11.60)	
Median	57.0	69.0	31.5	46.0	
Min, Max	16, 97	5, 95	30, 33	30, 63	
C7D1 CFB					
n	55	111	4	10	
LS Mean (StdErr) [2]	-1.18 (2.611)	6.89 (1.939)	11.50 (14.121)	-1.00 (10.812)	
95% CI [2]	-6.34, 3.97	3.06, 10.72	-19.96, 42.96	-25.09, 23.09	
Difference (95% CI) in CFB [2]		8.07 (2.47, 13.67)		-12.50 (-38.63, 13.63)	
Hedges'G (95% CI) in CFB		0.40 (0.08, 0.73)		-0.36 (-1.73, 0.87)	
p-value [3]		0.005		0.312	
					0.054

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-ecog-a.sas Date: 15:54/07AUG2023

Table 35.2.9.2.1.8a
Change from Baseline of EQ-5D-5L VAS by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	63	125	
Mean (StdDev)	61.3 (23.23)	46.2 (16.63)	55.6 (17.64)	58.1 (17.45)	
Median	57.5	40.5	60.0	60.0	
Min, Max	40, 90	26, 75	15, 94	15, 93	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-thpy-a.sas Date: 15:55/07AUG2023

Table 35.2.9.2.1.8a
Change from Baseline of EQ-5D-5L VAS by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	64	127	
Mean (StdDev)	67.5 (10.91)	57.1 (16.07)	56.9 (16.93)	60.0 (18.20)	
Median	68.0	60.0	60.0	60.0	
Min, Max	54, 80	32, 83	10, 81	20, 90	
C2D1 CFB					
n	4	10	61	122	
LS Mean (StdErr) [2]	3.78 (9.774)	5.55 (9.774)	1.06 (1.845)	1.69 (1.391)	
95% CI [2]	-18.00, 25.56	-16.22, 27.33	-2.58, 4.70	-1.05, 4.44	
Difference (95% CI) in CFB [2]		1.77 (-25.93, 29.47)		0.64 (-3.33, 4.61)	
p-value [3]		0.889		0.752	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-thpy-a.sas Date: 15:55/07AUG2023

Table 35.2.9.2.1.8a
Change from Baseline of EQ-5D-5L VAS by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	118	
Mean (StdDev)	63.0 (22.41)	58.3 (17.24)	57.6 (19.31)	64.4 (17.96)	
Median	71.0	60.5	61.0	69.0	
Min, Max	30, 80	30, 80	12, 90	14, 96	
C3D1 CFB					
n	4	10	59	115	
LS Mean (StdErr) [2]	-1.03 (10.570)	2.36 (10.570)	1.57 (2.187)	6.95 (1.630)	
95% CI [2]	-24.58, 22.52	-21.19, 25.92	-2.75, 5.89	3.73, 10.17	
Difference (95% CI) in CFB [2]		3.40 (-26.56, 33.35)		5.38 (0.65, 10.11)	
p-value [3]		0.806		0.026	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-thpy-a.sas Date: 15:55/07AUG2023

Table 35.2.9.2.1.8a
Change from Baseline of EQ-5D-5L VAS by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	52.7 (22.81)	62.8 (15.13)	55.3 (18.10)	64.2 (18.53)	
Median	40.0	65.0	60.0	66.0	
Min, Max	39, 79	37, 85	19, 91	10, 95	
C4D1 CFB					
n	3	9	53	116	
LS Mean (StdErr) [2]	7.31 (15.409)	15.47 (11.557)	0.09 (2.434)	6.14 (1.792)	
95% CI [2]	-28.22, 42.85	-11.18, 42.12	-4.72, 4.89	2.60, 9.68	
Difference (95% CI) in CFB [2]		8.16 (-32.55, 48.86)		6.06 (0.87, 11.24)	
p-value [3]		0.656		0.022	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-thpy-a.sas Date: 15:55/07AUG2023

Table 35.2.9.2.1.8a
Change from Baseline of EQ-5D-5L VAS by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	117	
Mean (StdDev)	67.5 (9.57)	63.5 (15.38)	56.1 (18.57)	62.3 (18.57)	
Median	65.0	64.5	60.0	66.0	
Min, Max	60, 80	32, 80	10, 90	19, 93	
C5D1 CFB					
n	4	8	57	111	
LS Mean (StdErr) [2]	3.88 (10.685)	11.12 (10.685)	0.32 (2.432)	4.06 (1.832)	
95% CI [2]	-20.75, 28.52	-13.52, 35.75	-4.48, 5.13	0.44, 7.68	
Difference (95% CI) in CFB [2]		7.23 (-24.29, 38.75)		3.73 (-1.49, 8.95)	
p-value [3]		0.611		0.160	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-thpy-a.sas Date: 15:55/07AUG2023

Table 35.2.9.2.1.8a
Change from Baseline of EQ-5D-5L VAS by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	63.8 (14.93)	61.3 (20.37)	53.6 (19.12)	64.0 (18.54)	
Median	65.0	68.0	56.0	69.5	
Min, Max	45, 80	24, 90	15, 96	13, 97	
C6D1 CFB					
n	4	9	55	114	
LS Mean (StdErr) [2]	0.89 (13.760)	12.44 (13.760)	-1.01 (2.295)	5.57 (1.685)	
95% CI [2]	-30.23, 32.02	-18.69, 43.57	-5.54, 3.52	2.25, 8.90	
Difference (95% CI) in CFB [2]		11.54 (-28.15, 51.23)		6.58 (1.64, 11.52)	
p-value [3]		0.527		0.009	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-thpy-a.sas Date: 15:55/07AUG2023

Table 35.2.9.2.1.8a
Change from Baseline of EQ-5D-5L VAS by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	64.0 (11.89)	68.3 (12.14)	55.6 (20.30)	63.5 (19.09)	
Median	64.0	67.5	55.0	67.0	
Min, Max	50, 78	50, 90	16, 97	5, 95	
C7D1 CFB					
n	4	8	55	113	
LS Mean (StdErr) [2]	1.12 (12.590)	15.88 (12.590)	-0.35 (2.621)	5.31 (1.936)	
95% CI [2]	-27.92, 30.15	-13.15, 44.92	-5.53, 4.83	1.49, 9.13	
Difference (95% CI) in CFB [2]		14.77 (-22.37, 51.91)		5.66 (0.11, 11.20)	
Hedges'G (95% CI) in CFB		0.42 (-0.86, 1.90)		0.28 (-0.04, 0.61)	
p-value [3]		0.386		0.046	
					0.341

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.4
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-g-itt-thpy-a.sas Date: 15:55/07AUG2023

Table 35.2.9.4.1a
Proportion of Patients with >=15 Points Increase in EQ-5D-5L VAS at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1 with EQ-5D-5L VAS at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 15 Points Increase at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	7/ 71 (9.9) (4.1, 19.3)	40/141 (28.4) (21.1, 36.6)	3.65 (1.46, 10.06) 0.002	2.88 (1.36, 6.12) 0.006	0.18 (0.08, 0.29) <0.001	
Age Group (Years)						0.976
< 65	7/ 60 (11.7) (4.8, 22.6)	35/132 (26.5) (19.2, 34.9)	2.71 (1.06, 7.59) 0.025	2.25 (1.06, 4.78) 0.036	0.15 (0.03, 0.26) 0.010	
>= 65	0/ 11 (0.0) (0.0, 28.5)	5/ 9 (55.6) (21.2, 86.3)	NE (1.19, NE) 0.020	NE (NE, NE) NE	0.50 (0.13, 0.87) 0.008	
Sex						0.864
Male	2/ 17 (11.8) (1.5, 36.4)	12/ 41 (29.3) (16.1, 45.5)	3.16 (0.56, 32.93) 0.158	2.47 (0.62, 9.83) 0.198	0.17 (-0.03, 0.38) 0.097	
Female	5/ 54 (9.3) (3.1, 20.3)	28/100 (28.0) (19.5, 37.9)	3.94 (1.37, 14.22) 0.005	3.10 (1.28, 7.52) 0.012	0.19 (0.08, 0.31) 0.001	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-resp-itt-a.sas Date: 15:02/14APR2023

Table 35.2.9.4.1a
Proportion of Patients with >=15 Points Increase in EQ-5D-5L VAS at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1 with EQ-5D-5L VAS at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 15 Points Increase at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Region						0.399
North America	2/ 33 (6.1) (0.7, 20.2)	17/ 60 (28.3) (17.5, 41.4)	7.00 (1.31, 60.42) 0.010	5.20 (1.17, 23.14) 0.030	0.23 (0.09, 0.37) 0.001	
Europe	5/ 38 (13.2) (4.4, 28.1)	23/ 81 (28.4) (18.9, 39.5)	2.59 (0.84, 9.33) 0.074	2.15 (0.88, 5.22) 0.092	0.15 (0.01, 0.30) 0.042	
Country						0.999
BEL	0/ 1 (0.0) (0.0, 97.5)	0/ 3 (0.0) (0.0, 70.8)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
CAN	0/ 5 (0.0) (0.0, 52.2)	1/ 8 (12.5) (0.3, 52.7)	NE (0.01, NE) 0.655	NE (NE, NE) NE	0.08 (-0.18, 0.34) 0.540	
CHE	0/ 1 (0.0) (0.0, 97.5)	0/ 2 (0.0) (0.0, 84.2)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DEU	2/ 15 (13.3) (1.7, 40.5)	5/ 19 (26.3) (9.1, 51.2)	2.16 (0.31, 30.73) 0.321	1.95 (0.48, 7.84) 0.349	0.14 (-0.15, 0.43) 0.338	
DNK	0/0	1/ 1 (100.0) (2.5, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-resp-itt-a.sas Date: 15:02/14APR2023

Table 35.2.9.4.1a
Proportion of Patients with >=15 Points Increase in EQ-5D-5L VAS at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1 with EQ-5D-5L VAS at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 15 Points Increase at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
ESP	0/ 3 (0.0) (0.0, 70.8)	3/ 14 (21.4) (4.7, 50.8)	NE (0.15, NE) 0.335	NE (NE, NE) NE	0.27 (0.02, 0.53) 0.038	
FRA	2/ 6 (33.3) (4.3, 77.7)	4/ 11 (36.4) (10.9, 69.2)	2.37 (0.13, 137.53) 0.529	1.69 (0.29, 9.92) 0.563	0.17 (-0.30, 0.64) 0.475	
GBR	0/ 5 (0.0) (0.0, 52.2)	4/ 11 (36.4) (10.9, 69.2)	NE (0.08, NE) 0.221	NE (NE, NE) NE	0.20 (-0.09, 0.49) 0.184	
ITA	0/0	1/ 4 (25.0) (0.6, 80.6)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
NLD	0/ 3 (0.0) (0.0, 70.8)	2/ 9 (22.2) (2.8, 60.0)	NE (0.05, NE) 0.317	NE (NE, NE) NE	0.33 (-0.20, 0.87) 0.221	
NOR	1/ 3 (33.3) (0.8, 90.6)	3/ 5 (60.0) (14.7, 94.7)	2.40 (0.08, 157.08) 0.541	1.70 (0.30, 9.62) 0.549	0.25 (-0.50, 1.00) 0.514	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-resp-itt-a.sas Date: 15:02/14APR2023

Table 35.2.9.4.1a
Proportion of Patients with >=15 Points Increase in EQ-5D-5L VAS at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1 with EQ-5D-5L VAS at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 15 Points Increase at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
SWE	0/ 1 (0.0) (0.0, 97.5)	0/ 2 (0.0) (0.0, 84.2)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
USA	2/ 28 (7.1) (0.9, 23.5)	16/ 52 (30.8) (18.7, 45.1)	7.22 (1.24, 60.72) 0.013	5.06 (1.11, 23.01) 0.036	0.25 (0.09, 0.41) 0.002	
Baseline ISM Status						0.583
Moderate	2/ 26 (7.7) (0.9, 25.1)	15/ 52 (28.8) (17.1, 43.1)	5.39 (1.03, 50.87) 0.027	3.96 (0.97, 16.15) 0.055	0.22 (0.06, 0.38) 0.006	
Severe	5/ 45 (11.1) (3.7, 24.1)	24/ 87 (27.6) (18.5, 38.2)	3.01 (1.00, 10.77) 0.033	2.46 (1.01, 6.01) 0.048	0.16 (0.03, 0.29) 0.015	
Baseline Serum Tryptase (ng/mL)						0.947
< 20	1/ 15 (6.7) (0.2, 31.9)	6/ 28 (21.4) (8.3, 41.0)	4.46 (0.41, 209.08) 0.189	3.59 (0.44, 29.03) 0.230	0.16 (-0.04, 0.36) 0.110	
>= 20	6/ 56 (10.7) (4.0, 21.9)	34/113 (30.1) (21.8, 39.4)	3.52 (1.32, 10.93) 0.006	2.78 (1.24, 6.22) 0.013	0.19 (0.07, 0.31) 0.001	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-resp-itt-a.sas Date: 15:02/14APR2023

Table 35.2.9.4.1a
Proportion of Patients with >=15 Points Increase in EQ-5D-5L VAS at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1 with EQ-5D-5L VAS at Baseline, Part 2 (Part 2 Baseline)

Patients with >= 15 Points Increase at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.982
0 or 1	7/ 67 (10.4) (4.3, 20.3)	39/131 (29.8) (22.1, 38.4)	3.68 (1.46, 10.14) 0.003	2.85 (1.35, 6.05) 0.006	0.19 (0.09, 0.30) <0.001	
2+	0/ 4 (0.0) (0.0, 60.2)	1/ 10 (10.0) (0.3, 44.5)	NE (0.04, NE) 0.414	NE (NE, NE) NE	0.15 (-0.08, 0.38) 0.213	
Prior TKI therapy						0.840
Yes	1/ 4 (25.0) (0.6, 80.6)	6/ 10 (60.0) (26.2, 87.8)	3.50 (0.16, 196.59) 0.317	3.50 (0.13, 95.14) 0.457	0.38 (-0.29, 1.00) 0.266	
No	6/ 67 (9.0) (3.4, 18.5)	34/131 (26.0) (18.7, 34.3)	3.50 (1.33, 10.72) 0.006	2.88 (1.26, 6.60) 0.012	0.17 (0.06, 0.27) 0.001	

Abbreviations: EQ-5D-5L = EuroQol-5 Dimensions-5 Levels, VAS = Visual Analogue Scale, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-eq5d-vas-resp-itt-a.sas Date: 15:02/14APR2023

Table 35.2.7.1.2a
Summary of PGIC by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	15	39	52	98	
Mean (StdDev)	2.8 (1.66)	3.2 (1.57)	2.6 (1.45)	3.3 (1.72)	
Median	2.0	3.0	2.0	3.0	
Min, Max	1, 5	1, 7	1, 6	1, 7	
LS Mean (StdErr) [2]	2.95 (0.444)	3.30 (0.287)	2.57 (0.256)	3.31 (0.210)	
95% CI [2]	2.06, 3.84	2.72, 3.87	2.06, 3.07	2.89, 3.72	
Difference (95% CI) [2]		0.35 (-0.63, 1.34)		0.74 (0.17, 1.30)	
p-value [3]		0.476		0.011	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-sex-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.2a
Summary of PGIC by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	49	94	
Mean (StdDev)	2.8 (1.79)	3.9 (1.78)	3.0 (1.56)	4.1 (1.69)	
Median	2.0	4.0	3.0	4.0	
Min, Max	1, 6	1, 7	1, 7	1, 7	
LS Mean (StdErr) [2]	2.51 (0.455)	3.59 (0.341)	2.94 (0.265)	4.05 (0.211)	
95% CI [2]	1.59, 3.42	2.90, 4.28	2.42, 3.47	3.63, 4.47	
Difference (95% CI) [2]		1.08 (0.02, 2.14)		1.11 (0.52, 1.69)	
p-value [3]		0.045		<0.001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-sex-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.2a
Summary of PGIC by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	92	
Mean (StdDev)	2.5 (1.51)	3.9 (1.73)	2.8 (1.80)	4.2 (1.73)	
Median	2.0	4.0	2.0	5.0	
Min, Max	1, 5	1, 7	1, 7	1, 7	
LS Mean (StdErr) [2]	2.30 (0.450)	3.68 (0.327)	2.64 (0.294)	4.05 (0.231)	
95% CI [2]	1.40, 3.21	3.03, 4.34	2.05, 3.22	3.60, 4.51	
Difference (95% CI) [2]		1.38 (0.35, 2.42)		1.42 (0.78, 2.05)	
p-value [3]		0.010		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-sex-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.2a
Summary of PGIC by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	88	
Mean (StdDev)	2.8 (1.79)	4.4 (1.52)	2.6 (1.69)	4.2 (1.81)	
Median	2.0	5.0	2.0	5.0	
Min, Max	1, 6	1, 7	1, 6	1, 7	
LS Mean (StdErr) [2]	2.62 (0.417)	4.25 (0.307)	2.62 (0.290)	4.24 (0.232)	
95% CI [2]	1.78, 3.45	3.64, 4.87	2.04, 3.19	3.78, 4.70	
Difference (95% CI) [2]		1.64 (0.68, 2.60)		1.62 (0.98, 2.27)	
p-value [3]		0.001		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-sex-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.2a
Summary of PGIC by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	90	
Mean (StdDev)	2.3 (1.54)	4.2 (1.81)	2.7 (1.75)	4.3 (1.85)	
Median	2.0	5.0	2.0	5.0	
Min, Max	1, 5	1, 7	1, 7	1, 7	
LS Mean (StdErr) [2]	2.23 (0.473)	4.12 (0.322)	2.61 (0.293)	4.25 (0.233)	
95% CI [2]	1.28, 3.18	3.47, 4.76	2.03, 3.19	3.79, 4.71	
Difference (95% CI) [2]		1.89 (0.81, 2.97)		1.64 (0.99, 2.29)	
p-value [3]		<0.001		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-sex-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.2a
Summary of PGIC by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	3.0 (1.93)	4.1 (1.53)	2.7 (1.86)	4.4 (1.78)	
Median	2.0	4.5	2.0	5.0	
Min, Max	1, 6	1, 6	1, 7	1, 7	
LS Mean (StdErr) [2]	2.92 (0.441)	4.05 (0.307)	2.67 (0.303)	4.35 (0.241)	
95% CI [2]	2.03, 3.80	3.43, 4.66	2.08, 3.27	3.87, 4.83	
Difference (95% CI) [2]		1.13 (0.12, 2.14)		1.68 (1.02, 2.33)	
Hedges'G (95% CI)		0.60 (0.02, 1.24)		0.76 (0.40, 1.14)	
p-value [3]		0.029		<0.0001	
					0.372

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-sex-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.2a
Summary of PGIC by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	15	39	52	98	
Mean (StdDev)	4.3 (1.76)	4.0 (1.44)	4.5 (1.08)	4.3 (1.62)	
Median	5.0	4.0	5.0	4.0	
Min, Max	0, 8	1, 6	1, 8	0, 8	
LS Mean (StdErr) [2]	4.52 (0.424)	4.13 (0.274)	4.52 (0.228)	4.31 (0.187)	
95% CI [2]	3.67, 5.37	3.58, 4.68	4.07, 4.97	3.94, 4.68	
Difference (95% CI) [2]		-0.39 (-1.33, 0.55)		-0.21 (-0.71, 0.29)	
p-value [3]		0.404		0.410	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-sex-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.2a
Summary of PGIC by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	49	93	
Mean (StdDev)	4.5 (1.77)	3.5 (1.33)	4.4 (1.24)	3.7 (1.69)	
Median	5.0	3.0	5.0	4.0	
Min, Max	1, 7	1, 6	1, 7	0, 9	
LS Mean (StdErr) [2]	4.74 (0.374)	3.75 (0.280)	4.39 (0.250)	3.66 (0.199)	
95% CI [2]	3.99, 5.49	3.19, 4.31	3.89, 4.88	3.26, 4.05	
Difference (95% CI) [2]		-0.99 (-1.86, -0.12)		-0.73 (-1.28, -0.18)	
p-value [3]		0.026		0.010	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-sex-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.2a
Summary of PGIC by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	92	
Mean (StdDev)	4.6 (1.64)	3.4 (1.44)	4.7 (1.66)	3.8 (1.63)	
Median	5.0	3.0	5.0	4.0	
Min, Max	1, 7	1, 7	1, 8	0, 9	
LS Mean (StdErr) [2]	4.67 (0.401)	3.51 (0.292)	4.75 (0.278)	3.85 (0.218)	
95% CI [2]	3.86, 5.47	2.92, 4.09	4.20, 5.30	3.42, 4.28	
Difference (95% CI) [2]		-1.16 (-2.08, -0.24)		-0.90 (-1.50, -0.30)	
p-value [3]		0.015		0.004	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-sex-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.2a
Summary of PGIC by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	88	
Mean (StdDev)	4.7 (1.69)	3.5 (1.46)	4.8 (1.33)	3.6 (1.76)	
Median	5.0	3.5	5.0	3.0	
Min, Max	2, 9	0, 7	2, 7	0, 9	
LS Mean (StdErr) [2]	5.05 (0.347)	3.92 (0.256)	4.79 (0.264)	3.62 (0.211)	
95% CI [2]	4.35, 5.75	3.40, 4.43	4.26, 5.31	3.20, 4.03	
Difference (95% CI) [2]		-1.13 (-1.93, -0.33)		-1.17 (-1.75, -0.58)	
p-value [3]		0.006		<0.001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-sex-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.2a
Summary of PGIC by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	90	
Mean (StdDev)	5.0 (1.60)	3.8 (1.63)	4.8 (1.58)	3.8 (1.90)	
Median	5.0	3.5	5.0	4.0	
Min, Max	3, 8	1, 8	0, 7	0, 9	
LS Mean (StdErr) [2]	5.03 (0.434)	3.87 (0.295)	4.75 (0.289)	3.65 (0.230)	
95% CI [2]	4.16, 5.90	3.28, 4.46	4.18, 5.32	3.19, 4.10	
Difference (95% CI) [2]		-1.16 (-2.15, -0.17)		-1.10 (-1.74, -0.47)	
p-value [3]		0.023		<0.001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-sex-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.2a
Summary of PGIC by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	4.9 (1.31)	3.8 (1.41)	4.9 (1.63)	3.5 (1.96)	
Median	5.0	4.0	5.0	3.0	
Min, Max	3, 7	0, 7	1, 8	0, 9	
LS Mean (StdErr) [2]	4.83 (0.359)	3.79 (0.250)	4.84 (0.312)	3.45 (0.248)	
95% CI [2]	4.11, 5.55	3.29, 4.30	4.22, 5.45	2.96, 3.94	
Difference (95% CI) [2]		-1.04 (-1.86, -0.22)		-1.39 (-2.06, -0.71)	
Hedges'G (95% CI)		-0.68 (-1.32, -0.09)		-0.61 (-0.98, -0.25)	
p-value [3]		0.014		<0.0001	
					0.591

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-sex-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.3a
Summary of PGIC by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	29	59	38	78	
Mean (StdDev)	2.5 (1.53)	3.2 (1.61)	2.7 (1.47)	3.4 (1.73)	
Median	2.0	3.0	2.0	3.0	
Min, Max	1, 6	1, 7	1, 5	1, 7	
LS Mean (StdErr) [2]	2.71 (0.322)	3.34 (0.250)	2.63 (0.296)	3.29 (0.224)	
95% CI [2]	2.07, 3.35	2.85, 3.84	2.04, 3.22	2.85, 3.74	
Difference (95% CI) [2]		0.64 (-0.08, 1.35)		0.66 (0.01, 1.31)	
p-value [3]		0.081		0.047	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-reg-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.3a
Summary of PGIC by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	29	52	37	76	
Mean (StdDev)	2.7 (1.65)	4.0 (1.54)	3.1 (1.58)	4.1 (1.83)	
Median	2.0	4.0	3.0	4.0	
Min, Max	1, 7	1, 6	1, 6	1, 7	
LS Mean (StdErr) [2]	2.53 (0.320)	3.84 (0.267)	3.03 (0.313)	3.98 (0.232)	
95% CI [2]	1.90, 3.17	3.31, 4.38	2.41, 3.65	3.52, 4.43	
Difference (95% CI) [2]		1.31 (0.57, 2.05)		0.94 (0.25, 1.63)	
p-value [3]		<0.001		0.008	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-reg-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.3a
Summary of PGIC by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	51	37	77	
Mean (StdDev)	2.8 (1.85)	4.0 (1.60)	2.6 (1.67)	4.2 (1.81)	
Median	2.0	4.0	2.0	5.0	
Min, Max	1, 7	1, 6	1, 6	1, 7	
LS Mean (StdErr) [2]	2.65 (0.376)	3.79 (0.302)	2.54 (0.315)	4.11 (0.234)	
95% CI [2]	1.90, 3.40	3.19, 4.39	1.91, 3.16	3.65, 4.58	
Difference (95% CI) [2]		1.14 (0.31, 1.98)		1.58 (0.88, 2.27)	
p-value [3]		0.008		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-reg-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.3a
Summary of PGIC by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	46	37	78	
Mean (StdDev)	2.6 (1.74)	4.2 (1.67)	2.6 (1.71)	4.3 (1.77)	
Median	2.0	5.0	2.0	5.0	
Min, Max	1, 6	1, 6	1, 6	1, 7	
LS Mean (StdErr) [2]	2.78 (0.356)	4.31 (0.299)	2.52 (0.312)	4.21 (0.230)	
95% CI [2]	2.07, 3.49	3.72, 4.91	1.91, 3.14	3.75, 4.66	
Difference (95% CI) [2]		1.53 (0.70, 2.36)		1.69 (1.00, 2.37)	
p-value [3]		<0.001		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-reg-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.3a
Summary of PGIC by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	51	37	77	
Mean (StdDev)	2.8 (1.94)	4.4 (1.72)	2.4 (1.52)	4.2 (1.91)	
Median	2.0	5.0	2.0	5.0	
Min, Max	1, 7	1, 7	1, 6	1, 7	
LS Mean (StdErr) [2]	2.89 (0.389)	4.42 (0.305)	2.25 (0.315)	4.04 (0.232)	
95% CI [2]	2.12, 3.67	3.81, 5.03	1.62, 2.87	3.58, 4.50	
Difference (95% CI) [2]		1.53 (0.64, 2.43)		1.79 (1.10, 2.49)	
p-value [3]		0.001		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-reg-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.3a
Summary of PGIC by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	2.9 (2.10)	4.5 (1.49)	2.7 (1.72)	4.2 (1.84)	
Median	2.0	5.0	2.0	4.0	
Min, Max	1, 7	1, 6	1, 6	1, 7	
LS Mean (StdErr) [2]	3.08 (0.384)	4.65 (0.309)	2.51 (0.322)	4.02 (0.238)	
95% CI [2]	2.31, 3.84	4.04, 5.27	1.87, 3.15	3.55, 4.49	
Difference (95% CI) [2]		1.58 (0.72, 2.43)		1.51 (0.80, 2.22)	
Hedges'G (95% CI)		0.74 (0.26, 1.27)		0.73 (0.34, 1.16)	
p-value [3]		<0.001		<0.0001	
					0.944

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-reg-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.3a
Summary of PGIC by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	29	59	38	78	
Mean (StdDev)	4.2 (1.31)	4.3 (1.33)	4.7 (1.16)	4.1 (1.74)	
Median	4.0	5.0	5.0	4.0	
Min, Max	0, 6	1, 8	2, 8	0, 8	
LS Mean (StdErr) [2]	4.16 (0.274)	4.34 (0.213)	4.79 (0.282)	4.20 (0.214)	
95% CI [2]	3.62, 4.71	3.91, 4.76	4.23, 5.35	3.77, 4.62	
Difference (95% CI) [2]		0.18 (-0.43, 0.79)		-0.60 (-1.22, 0.03)	
p-value [3]		0.567		0.060	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-reg-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.3a
Summary of PGIC by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	29	51	37	76	
Mean (StdDev)	4.4 (1.45)	3.7 (1.24)	4.5 (1.35)	3.6 (1.81)	
Median	5.0	4.0	5.0	3.5	
Min, Max	1, 7	1, 7	1, 7	0, 9	
LS Mean (StdErr) [2]	4.38 (0.273)	3.71 (0.228)	4.57 (0.303)	3.67 (0.224)	
95% CI [2]	3.83, 4.92	3.26, 4.17	3.97, 5.17	3.23, 4.12	
Difference (95% CI) [2]		-0.66 (-1.30, -0.03)		-0.89 (-1.56, -0.23)	
p-value [3]		0.040		0.009	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-reg-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.3a
Summary of PGIC by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	51	37	77	
Mean (StdDev)	4.4 (1.80)	3.8 (1.26)	4.9 (1.53)	3.6 (1.77)	
Median	5.0	4.0	5.0	4.0	
Min, Max	1, 7	1, 8	2, 8	0, 9	
LS Mean (StdErr) [2]	4.36 (0.333)	3.75 (0.267)	4.87 (0.303)	3.63 (0.225)	
95% CI [2]	3.70, 5.03	3.22, 4.28	4.27, 5.47	3.19, 4.08	
Difference (95% CI) [2]		-0.62 (-1.35, 0.12)		-1.24 (-1.91, -0.57)	
p-value [3]		0.101		<0.001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-reg-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.3a
Summary of PGIC by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	46	37	78	
Mean (StdDev)	4.6 (1.52)	3.7 (1.40)	4.9 (1.35)	3.6 (1.82)	
Median	5.0	3.0	5.0	4.0	
Min, Max	2, 7	2, 7	2, 9	0, 9	
LS Mean (StdErr) [2]	4.56 (0.305)	3.57 (0.256)	5.03 (0.304)	3.71 (0.225)	
95% CI [2]	3.95, 5.17	3.06, 4.08	4.43, 5.63	3.27, 4.16	
Difference (95% CI) [2]		-0.98 (-1.69, -0.27)		-1.32 (-1.99, -0.65)	
p-value [3]		0.007		<0.001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-reg-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.3a
Summary of PGIC by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	51	37	77	
Mean (StdDev)	4.4 (1.85)	4.1 (1.76)	5.2 (1.30)	3.5 (1.83)	
Median	5.0	4.0	5.0	3.0	
Min, Max	0, 8	1, 8	2, 8	0, 9	
LS Mean (StdErr) [2]	4.21 (0.374)	3.84 (0.293)	5.22 (0.304)	3.61 (0.224)	
95% CI [2]	3.47, 4.96	3.25, 4.42	4.62, 5.82	3.17, 4.06	
Difference (95% CI) [2]		-0.37 (-1.23, 0.49)		-1.61 (-2.28, -0.94)	
p-value [3]		0.390		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-reg-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.3a
Summary of PGIC by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	4.6 (1.68)	3.7 (1.62)	5.1 (1.43)	3.5 (1.94)	
Median	5.0	3.0	5.0	3.0	
Min, Max	1, 8	1, 8	2, 8	0, 9	
LS Mean (StdErr) [2]	4.36 (0.363)	3.51 (0.292)	5.13 (0.325)	3.55 (0.240)	
95% CI [2]	3.64, 5.09	2.93, 4.09	4.48, 5.77	3.07, 4.02	
Difference (95% CI) [2]		-0.85 (-1.66, -0.05)		-1.58 (-2.30, -0.87)	
Hedges'G (95% CI)		-0.43 (-0.93, 0.05)		-0.76 (-1.19, -0.37)	
p-value [3]		0.039		<0.0001	
					0.181

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-reg-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.4a
Summary of PGIC by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-cou-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.4a
Summary of PGIC by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-cou-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.4a
Summary of PGIC by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-cou-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.4a
Summary of PGIC by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-cou-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.4a
Summary of PGIC by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-cou-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.4a
Summary of PGIC by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-cou-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.4a
Summary of PGIC by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-cou-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.4a
Summary of PGIC by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-cou-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.4a
Summary of PGIC by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-cou-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.4a
Summary of PGIC by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-cou-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.5a
Summary of PGIC by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	24	50	43	85	
Mean (StdDev)	2.3 (1.33)	3.3 (1.72)	2.8 (1.55)	3.2 (1.67)	
Median	2.0	3.0	2.0	3.0	
Min, Max	1, 5	1, 7	1, 6	1, 7	
LS Mean (StdErr) [2]	2.29 (0.375)	3.34 (0.260)	2.87 (0.265)	3.31 (0.213)	
95% CI [2]	1.55, 3.04	2.82, 3.86	2.34, 3.39	2.89, 3.73	
Difference (95% CI) [2]		1.05 (0.24, 1.86)		0.44 (-0.17, 1.05)	
p-value [3]		0.012		0.156	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-ism-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.5a
Summary of PGIC by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	44	78	
Mean (StdDev)	2.7 (1.62)	4.2 (1.71)	3.0 (1.61)	3.9 (1.73)	
Median	2.0	4.5	2.0	4.0	
Min, Max	1, 6	1, 7	1, 7	1, 7	
LS Mean (StdErr) [2]	2.44 (0.387)	4.00 (0.274)	2.97 (0.271)	3.83 (0.223)	
95% CI [2]	1.66, 3.21	3.45, 4.55	2.43, 3.50	3.39, 4.27	
Difference (95% CI) [2]		1.56 (0.71, 2.42)		0.86 (0.23, 1.49)	
p-value [3]		<0.001		0.008	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-ism-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.5a
Summary of PGIC by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	80	
Mean (StdDev)	2.3 (1.59)	4.3 (1.65)	2.9 (1.78)	4.1 (1.78)	
Median	2.0	5.0	2.0	4.0	
Min, Max	1, 6	1, 7	1, 7	1, 7	
LS Mean (StdErr) [2]	2.14 (0.387)	4.07 (0.284)	2.79 (0.305)	3.91 (0.236)	
95% CI [2]	1.36, 2.91	3.50, 4.63	2.19, 3.40	3.44, 4.38	
Difference (95% CI) [2]		1.93 (1.08, 2.79)		1.12 (0.43, 1.81)	
p-value [3]		<0.0001		0.002	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-ism-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.5a
Summary of PGIC by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	41	77	
Mean (StdDev)	2.5 (1.65)	4.5 (1.56)	2.7 (1.75)	4.1 (1.82)	
Median	2.0	5.0	2.0	5.0	
Min, Max	1, 6	1, 7	1, 6	1, 7	
LS Mean (StdErr) [2]	2.50 (0.369)	4.55 (0.274)	2.63 (0.299)	4.02 (0.236)	
95% CI [2]	1.76, 3.24	4.01, 5.10	2.04, 3.23	3.55, 4.49	
Difference (95% CI) [2]		2.05 (1.23, 2.87)		1.39 (0.70, 2.08)	
p-value [3]		<0.0001		<0.001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-ism-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.5a
Summary of PGIC by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	78	
Mean (StdDev)	2.4 (1.59)	4.6 (1.76)	2.7 (1.77)	4.1 (1.86)	
Median	2.0	5.0	2.0	4.0	
Min, Max	1, 6	1, 7	1, 7	1, 7	
LS Mean (StdErr) [2]	2.34 (0.393)	4.53 (0.282)	2.53 (0.309)	3.92 (0.239)	
95% CI [2]	1.56, 3.13	3.96, 5.09	1.92, 3.15	3.44, 4.39	
Difference (95% CI) [2]		2.19 (1.32, 3.06)		1.38 (0.67, 2.09)	
p-value [3]		<0.0001		<0.001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-ism-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.5a
Summary of PGIC by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	2.7 (1.78)	4.5 (1.52)	2.8 (1.94)	4.2 (1.83)	
Median	2.0	5.0	2.0	5.0	
Min, Max	1, 6	1, 7	1, 7	1, 7	
LS Mean (StdErr) [2]	2.68 (0.376)	4.43 (0.272)	2.70 (0.318)	4.08 (0.250)	
95% CI [2]	1.93, 3.43	3.89, 4.98	2.07, 3.33	3.59, 4.58	
Difference (95% CI) [2]		1.76 (0.93, 2.58)		1.38 (0.66, 2.11)	
Hedges'G (95% CI)		0.94 (0.43, 1.51)		0.64 (0.26, 1.05)	
p-value [3]		<0.0001		<0.001	
					0.515

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-ism-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.5a
Summary of PGIC by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	24	50	43	85	
Mean (StdDev)	4.6 (1.61)	4.2 (1.37)	4.4 (1.00)	4.2 (1.70)	
Median	5.0	4.5	5.0	4.0	
Min, Max	0, 8	1, 7	1, 6	0, 8	
LS Mean (StdErr) [2]	4.87 (0.333)	4.37 (0.231)	4.35 (0.244)	4.17 (0.196)	
95% CI [2]	4.21, 5.54	3.91, 4.83	3.87, 4.83	3.78, 4.55	
Difference (95% CI) [2]		-0.50 (-1.22, 0.22)		-0.19 (-0.75, 0.37)	
p-value [3]		0.169		0.513	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-ism-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.5a
Summary of PGIC by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	44	77	
Mean (StdDev)	4.4 (1.53)	3.6 (1.40)	4.5 (1.32)	3.7 (1.74)	
Median	5.0	3.5	5.0	4.0	
Min, Max	1, 7	1, 8	1, 7	0, 9	
LS Mean (StdErr) [2]	4.54 (0.335)	3.71 (0.237)	4.47 (0.258)	3.68 (0.213)	
95% CI [2]	3.87, 5.21	3.24, 4.19	3.96, 4.98	3.26, 4.10	
Difference (95% CI) [2]		-0.82 (-1.56, -0.08)		-0.79 (-1.39, -0.19)	
p-value [3]		0.030		0.011	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-ism-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.5a
Summary of PGIC by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	80	
Mean (StdDev)	4.4 (1.36)	3.7 (1.55)	4.9 (1.76)	3.7 (1.63)	
Median	5.0	4.0	5.0	4.0	
Min, Max	1, 7	1, 8	1, 8	0, 9	
LS Mean (StdErr) [2]	4.40 (0.359)	3.67 (0.264)	4.90 (0.288)	3.77 (0.223)	
95% CI [2]	3.68, 5.12	3.14, 4.20	4.33, 5.47	3.33, 4.21	
Difference (95% CI) [2]		-0.73 (-1.52, 0.06)		-1.13 (-1.78, -0.48)	
p-value [3]		0.071		<0.001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-ism-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.5a
Summary of PGIC by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	41	77	
Mean (StdDev)	4.8 (1.13)	3.5 (1.52)	4.8 (1.57)	3.7 (1.76)	
Median	5.0	3.0	5.0	3.0	
Min, Max	3, 7	0, 8	2, 9	0, 9	
LS Mean (StdErr) [2]	4.76 (0.325)	3.45 (0.241)	4.88 (0.283)	3.81 (0.223)	
95% CI [2]	4.11, 5.41	2.97, 3.93	4.32, 5.44	3.36, 4.25	
Difference (95% CI) [2]		-1.31 (-2.03, -0.59)		-1.08 (-1.73, -0.43)	
p-value [3]		<0.001		0.001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-ism-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.5a
Summary of PGIC by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	78	
Mean (StdDev)	5.0 (1.24)	3.6 (1.61)	4.8 (1.75)	3.8 (1.91)	
Median	5.0	3.0	5.0	4.0	
Min, Max	2, 7	0, 8	0, 8	0, 9	
LS Mean (StdErr) [2]	4.88 (0.345)	3.48 (0.248)	4.78 (0.316)	3.85 (0.244)	
95% CI [2]	4.19, 5.57	2.99, 3.98	4.16, 5.41	3.36, 4.33	
Difference (95% CI) [2]		-1.40 (-2.16, -0.63)		-0.93 (-1.66, -0.21)	
p-value [3]		<0.001		0.012	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-ism-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.5a
Summary of PGIC by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	5.0 (1.27)	3.4 (1.33)	4.9 (1.69)	3.8 (2.07)	
Median	5.0	3.0	5.0	4.0	
Min, Max	2, 7	0, 7	1, 8	0, 9	
LS Mean (StdErr) [2]	4.86 (0.306)	3.27 (0.221)	4.85 (0.333)	3.75 (0.261)	
95% CI [2]	4.25, 5.47	2.83, 3.71	4.19, 5.51	3.24, 4.27	
Difference (95% CI) [2]		-1.59 (-2.27, -0.92)		-1.10 (-1.85, -0.34)	
Hedges'G (95% CI)		-1.05 (-1.63, -0.54)		-0.49 (-0.89, -0.11)	
p-value [3]		<0.0001		0.005	
					0.377

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-ism-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.6a
Summary of PGIC by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	14	27	53	110	
Mean (StdDev)	3.4 (1.50)	3.1 (1.49)	2.4 (1.42)	3.3 (1.72)	
Median	3.5	2.0	2.0	3.0	
Min, Max	1, 6	1, 6	1, 6	1, 7	
LS Mean (StdErr) [2]	3.42 (0.430)	3.07 (0.293)	2.41 (0.227)	3.32 (0.163)	
95% CI [2]	2.55, 4.29	2.48, 3.67	1.96, 2.86	2.99, 3.64	
Difference (95% CI) [2]		-0.35 (-1.39, 0.69)		0.91 (0.36, 1.45)	
p-value [3]		0.499		0.001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-tryp-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.6a
Summary of PGIC by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	51	102	
Mean (StdDev)	3.1 (1.51)	3.3 (1.67)	2.9 (1.65)	4.2 (1.68)	
Median	3.0	4.0	2.0	5.0	
Min, Max	2, 7	1, 6	1, 6	1, 7	
LS Mean (StdErr) [2]	3.10 (0.440)	3.34 (0.323)	2.89 (0.239)	4.23 (0.172)	
95% CI [2]	2.21, 3.99	2.68, 3.99	2.41, 3.36	3.89, 4.57	
Difference (95% CI) [2]		0.24 (-0.85, 1.32)		1.34 (0.77, 1.92)	
p-value [3]		0.663		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-tryp-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.6a
Summary of PGIC by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	104	
Mean (StdDev)	2.7 (1.44)	3.5 (1.82)	2.7 (1.81)	4.3 (1.68)	
Median	2.0	3.0	2.0	5.0	
Min, Max	1, 6	1, 6	1, 7	1, 7	
LS Mean (StdErr) [2]	2.66 (0.490)	3.48 (0.359)	2.72 (0.256)	4.28 (0.176)	
95% CI [2]	1.67, 3.66	2.75, 4.21	2.21, 3.23	3.93, 4.63	
Difference (95% CI) [2]		0.82 (-0.39, 2.02)		1.56 (0.96, 2.16)	
p-value [3]		0.177		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-tryp-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.6a
Summary of PGIC by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	98	
Mean (StdDev)	3.0 (1.36)	3.9 (1.73)	2.5 (1.79)	4.4 (1.72)	
Median	3.0	4.0	2.0	5.0	
Min, Max	1, 6	1, 6	1, 6	1, 7	
LS Mean (StdErr) [2]	3.12 (0.445)	3.95 (0.321)	2.54 (0.251)	4.38 (0.184)	
95% CI [2]	2.22, 4.02	3.30, 4.60	2.04, 3.03	4.02, 4.74	
Difference (95% CI) [2]		0.83 (-0.26, 1.91)		1.85 (1.24, 2.45)	
p-value [3]		0.131		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-tryp-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.6a
Summary of PGIC by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	101	
Mean (StdDev)	2.8 (1.63)	3.7 (1.88)	2.5 (1.73)	4.5 (1.79)	
Median	2.0	4.0	2.0	5.0	
Min, Max	1, 7	1, 7	1, 7	1, 7	
LS Mean (StdErr) [2]	2.91 (0.497)	3.72 (0.351)	2.54 (0.258)	4.47 (0.183)	
95% CI [2]	1.91, 3.92	3.01, 4.43	2.03, 3.05	4.11, 4.83	
Difference (95% CI) [2]		0.81 (-0.40, 2.02)		1.93 (1.31, 2.55)	
p-value [3]		0.183		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-tryp-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.6a
Summary of PGIC by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	3.1 (1.71)	3.8 (1.89)	2.7 (1.92)	4.4 (1.64)	
Median	2.0	4.0	2.0	5.0	
Min, Max	1, 7	1, 7	1, 7	1, 7	
LS Mean (StdErr) [2]	3.16 (0.526)	3.84 (0.375)	2.71 (0.253)	4.44 (0.178)	
95% CI [2]	2.09, 4.23	3.08, 4.60	2.21, 3.21	4.09, 4.80	
Difference (95% CI) [2]		0.68 (-0.60, 1.97)		1.73 (1.13, 2.34)	
Hedges'G (95% CI)		0.36 (-0.32, 1.08)		0.96 (0.62, 1.34)	
p-value [3]		0.288		<0.0001	
					0.131

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-tryp-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.6a
Summary of PGIC by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	14	27	53	110	
Mean (StdDev)	4.4 (1.39)	4.4 (1.15)	4.5 (1.22)	4.2 (1.66)	
Median	4.0	5.0	5.0	4.0	
Min, Max	3, 8	2, 6	0, 8	0, 8	
LS Mean (StdErr) [2]	4.55 (0.343)	4.44 (0.234)	4.50 (0.213)	4.15 (0.153)	
95% CI [2]	3.85, 5.24	3.97, 4.92	4.08, 4.92	3.85, 4.45	
Difference (95% CI) [2]		-0.10 (-0.93, 0.72)		-0.35 (-0.86, 0.16)	
p-value [3]		0.801		0.181	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-tryp-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.6a
Summary of PGIC by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	51	101	
Mean (StdDev)	4.3 (1.50)	3.9 (1.16)	4.5 (1.36)	3.6 (1.69)	
Median	4.0	4.0	5.0	3.0	
Min, Max	1, 7	2, 6	1, 7	0, 9	
LS Mean (StdErr) [2]	4.37 (0.352)	3.94 (0.258)	4.45 (0.228)	3.55 (0.164)	
95% CI [2]	3.66, 5.08	3.41, 4.46	4.00, 4.90	3.22, 3.87	
Difference (95% CI) [2]		-0.44 (-1.30, 0.43)		-0.90 (-1.45, -0.36)	
p-value [3]		0.316		0.001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-tryp-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.6a
Summary of PGIC by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	104	
Mean (StdDev)	4.0 (1.91)	4.2 (1.38)	4.9 (1.52)	3.6 (1.61)	
Median	4.0	4.0	5.0	3.5	
Min, Max	1, 7	1, 7	1, 8	0, 9	
LS Mean (StdErr) [2]	3.93 (0.456)	4.17 (0.334)	4.87 (0.236)	3.56 (0.162)	
95% CI [2]	3.01, 4.86	3.49, 4.84	4.40, 5.33	3.24, 3.88	
Difference (95% CI) [2]		0.23 (-0.89, 1.35)		-1.31 (-1.86, -0.75)	
p-value [3]		0.678		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-tryp-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.6a
Summary of PGIC by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	98	
Mean (StdDev)	4.4 (1.65)	4.1 (1.26)	4.9 (1.35)	3.5 (1.75)	
Median	4.5	4.0	5.0	3.0	
Min, Max	2, 9	1, 7	2, 7	0, 9	
LS Mean (StdErr) [2]	4.30 (0.386)	4.01 (0.279)	4.87 (0.233)	3.47 (0.171)	
95% CI [2]	3.52, 5.08	3.44, 4.57	4.41, 5.34	3.14, 3.81	
Difference (95% CI) [2]		-0.29 (-1.23, 0.65)		-1.40 (-1.96, -0.84)	
p-value [3]		0.534		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-tryp-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.6a
Summary of PGIC by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	101	
Mean (StdDev)	4.2 (1.58)	3.9 (1.69)	5.0 (1.54)	3.7 (1.86)	
Median	5.0	4.0	5.0	3.0	
Min, Max	0, 6	0, 8	1, 8	0, 9	
LS Mean (StdErr) [2]	4.10 (0.456)	3.88 (0.322)	5.04 (0.255)	3.69 (0.180)	
95% CI [2]	3.18, 5.02	3.23, 4.53	4.54, 5.54	3.33, 4.04	
Difference (95% CI) [2]		-0.22 (-1.33, 0.89)		-1.35 (-1.96, -0.75)	
p-value [3]		0.686		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-tryp-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.6a
Summary of PGIC by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	4.1 (1.44)	3.8 (1.77)	5.1 (1.51)	3.5 (1.83)	
Median	4.0	4.0	5.0	3.0	
Min, Max	1, 6	0, 9	2, 8	0, 9	
LS Mean (StdErr) [2]	3.95 (0.473)	3.77 (0.337)	5.11 (0.252)	3.55 (0.178)	
95% CI [2]	2.99, 4.91	3.09, 4.46	4.61, 5.61	3.20, 3.90	
Difference (95% CI) [2]		-0.18 (-1.33, 0.98)		-1.56 (-2.16, -0.96)	
Hedges'G (95% CI)		-0.10 (-0.80, 0.59)		-0.87 (-1.24, -0.52)	
p-value [3]		0.758		<0.0001	
					0.044

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-tryp-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.7a
Summary of PGIC by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	63	128	4	9	
Mean (StdDev)	2.6 (1.47)	3.3 (1.67)	2.5 (1.91)	2.8 (1.79)	
Median	2.0	3.0	2.0	2.0	
Min, Max	1, 6	1, 7	1, 5	1, 6	
LS Mean (StdErr) [2]	2.68 (0.222)	3.36 (0.170)	1.89 (1.422)	2.15 (1.083)	
95% CI [2]	2.24, 3.12	3.02, 3.69	-1.33, 5.11	-0.30, 4.60	
Difference (95% CI) [2]		0.68 (0.19, 1.17)		0.26 (-2.43, 2.95)	
p-value [3]		0.007		0.831	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-ecog-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.7a
Summary of PGIC by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	62	119	4	9	
Mean (StdDev)	2.9 (1.60)	4.1 (1.74)	3.5 (1.91)	3.6 (1.24)	
Median	2.0	4.0	3.0	4.0	
Min, Max	1, 7	1, 7	2, 6	1, 5	
LS Mean (StdErr) [2]	2.78 (0.234)	3.94 (0.182)	3.65 (1.158)	3.59 (0.882)	
95% CI [2]	2.32, 3.24	3.58, 4.30	1.03, 6.27	1.59, 5.58	
Difference (95% CI) [2]		1.16 (0.63, 1.69)		-0.07 (-2.26, 2.13)	
p-value [3]		<0.0001		0.948	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-ecog-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.7a
Summary of PGIC by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	9	
Mean (StdDev)	2.8 (1.72)	4.1 (1.76)	2.0 (2.00)	4.1 (1.36)	
Median	2.0	5.0	1.0	5.0	
Min, Max	1, 7	1, 7	1, 5	2, 6	
LS Mean (StdErr) [2]	2.62 (0.253)	3.97 (0.193)	1.26 (1.215)	3.43 (0.925)	
95% CI [2]	2.12, 3.12	3.59, 4.35	-1.49, 4.01	1.34, 5.53	
Difference (95% CI) [2]		1.35 (0.79, 1.91)		2.17 (-0.13, 4.47)	
p-value [3]		<0.0001		0.061	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-ecog-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.7a
Summary of PGIC by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	115	4	9	
Mean (StdDev)	2.6 (1.72)	4.3 (1.74)	2.5 (1.73)	3.6 (1.42)	
Median	2.0	5.0	2.0	4.0	
Min, Max	1, 6	1, 7	1, 5	1, 5	
LS Mean (StdErr) [2]	2.62 (0.244)	4.30 (0.190)	2.26 (1.215)	3.43 (0.925)	
95% CI [2]	2.14, 3.10	3.92, 4.67	-0.49, 5.01	1.34, 5.53	
Difference (95% CI) [2]		1.68 (1.13, 2.23)		1.17 (-1.13, 3.47)	
p-value [3]		<0.0001		0.278	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-ecog-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.7a
Summary of PGIC by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	118	4	10	
Mean (StdDev)	2.6 (1.71)	4.3 (1.84)	2.5 (1.73)	3.7 (1.64)	
Median	2.0	5.0	2.0	4.0	
Min, Max	1, 7	1, 7	1, 5	2, 6	
LS Mean (StdErr) [2]	2.52 (0.254)	4.24 (0.192)	1.57 (1.266)	2.98 (0.969)	
95% CI [2]	2.01, 3.02	3.86, 4.62	-1.25, 4.40	0.82, 5.14	
Difference (95% CI) [2]		1.73 (1.16, 2.30)		1.41 (-0.94, 3.75)	
p-value [3]		<0.0001		0.210	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-ecog-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.7a
Summary of PGIC by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	2.8 (1.88)	4.4 (1.69)	2.3 (1.89)	3.4 (1.78)	
Median	2.0	5.0	1.5	4.0	
Min, Max	1, 7	1, 7	1, 5	1, 6	
LS Mean (StdErr) [2]	2.77 (0.252)	4.33 (0.192)	0.83 (1.311)	2.17 (1.004)	
95% CI [2]	2.27, 3.26	3.95, 4.70	-2.09, 3.75	-0.07, 4.40	
Difference (95% CI) [2]		1.56 (1.00, 2.12)		1.33 (-1.09, 3.76)	
Hedges'G (95% CI)		0.77 (0.45, 1.10)		0.41 (-0.81, 1.80)	
p-value [3]		<0.0001		0.249	
					0.751

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-ecog-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.7a
Summary of PGIC by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	63	128	4	9	
Mean (StdDev)	4.4 (1.19)	4.2 (1.57)	5.0 (2.16)	4.7 (1.66)	
Median	5.0	4.0	4.5	4.0	
Min, Max	0, 8	0, 8	3, 8	2, 8	
LS Mean (StdErr) [2]	4.49 (0.201)	4.23 (0.154)	4.74 (1.442)	4.57 (1.098)	
95% CI [2]	4.09, 4.89	3.93, 4.53	1.48, 8.00	2.08, 7.05	
Difference (95% CI) [2]		-0.26 (-0.71, 0.19)		-0.17 (-2.90, 2.56)	
p-value [3]		0.253		0.889	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-ecog-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.7a
Summary of PGIC by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	62	118	4	9	
Mean (StdDev)	4.5 (1.39)	3.6 (1.53)	4.3 (1.50)	4.8 (2.05)	
Median	5.0	3.0	5.0	4.0	
Min, Max	1, 7	0, 9	2, 5	2, 8	
LS Mean (StdErr) [2]	4.51 (0.206)	3.62 (0.161)	3.67 (1.516)	4.21 (1.154)	
95% CI [2]	4.11, 4.92	3.30, 3.94	0.24, 7.10	1.59, 6.82	
Difference (95% CI) [2]		-0.89 (-1.36, -0.43)		0.53 (-2.34, 3.40)	
p-value [3]		<0.001		0.684	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-ecog-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.7a
Summary of PGIC by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	9	
Mean (StdDev)	4.6 (1.66)	3.7 (1.62)	5.5 (1.29)	3.8 (0.97)	
Median	5.0	4.0	5.5	4.0	
Min, Max	1, 8	0, 9	4, 7	2, 5	
LS Mean (StdErr) [2]	4.63 (0.239)	3.70 (0.182)	6.20 (0.810)	4.33 (0.617)	
95% CI [2]	4.16, 5.10	3.34, 4.06	4.36, 8.03	2.93, 5.72	
Difference (95% CI) [2]		-0.93 (-1.46, -0.40)		-1.87 (-3.40, -0.34)	
p-value [3]		<0.001		0.022	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-ecog-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.7a
Summary of PGIC by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	115	4	9	
Mean (StdDev)	4.8 (1.42)	3.5 (1.63)	5.0 (1.63)	4.3 (2.06)	
Median	5.0	3.0	5.0	3.0	
Min, Max	2, 9	0, 9	3, 7	2, 8	
LS Mean (StdErr) [2]	4.82 (0.219)	3.61 (0.170)	3.89 (1.400)	3.65 (1.067)	
95% CI [2]	4.39, 5.25	3.28, 3.95	0.72, 7.06	1.24, 6.06	
Difference (95% CI) [2]		-1.21 (-1.70, -0.72)		-0.24 (-2.89, 2.41)	
p-value [3]		<0.0001		0.843	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-ecog-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.7a
Summary of PGIC by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	118	4	10	
Mean (StdDev)	4.9 (1.61)	3.7 (1.82)	4.8 (1.26)	4.3 (1.77)	
Median	5.0	4.0	5.0	4.0	
Min, Max	0, 8	0, 9	3, 6	2, 7	
LS Mean (StdErr) [2]	4.81 (0.246)	3.64 (0.186)	5.30 (1.261)	4.93 (0.966)	
95% CI [2]	4.32, 5.29	3.27, 4.00	2.49, 8.11	2.77, 7.08	
Difference (95% CI) [2]		-1.17 (-1.73, -0.62)		-0.37 (-2.70, 1.96)	
p-value [3]		<0.0001		0.731	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-ecog-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.7a
Summary of PGIC by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	4.9 (1.58)	3.6 (1.77)	5.5 (0.58)	4.0 (2.36)	
Median	5.0	3.0	5.5	4.0	
Min, Max	1, 8	0, 9	5, 6	0, 9	
LS Mean (StdErr) [2]	4.79 (0.246)	3.51 (0.188)	5.96 (1.622)	4.26 (1.242)	
95% CI [2]	4.30, 5.27	3.14, 3.88	2.35, 9.58	1.49, 7.03	
Difference (95% CI) [2]		-1.27 (-1.82, -0.73)		-1.70 (-4.70, 1.30)	
Hedges'G (95% CI)		-0.64 (-0.97, -0.32)		-0.42 (-1.81, 0.79)	
p-value [3]		<0.0001		0.235	
					0.814

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-ecog-a.sas Date: 15:49/07AUG2023

Table 35.2.7.1.8a
Summary of PGIC by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	63	127	
Mean (StdDev)	2.8 (1.50)	2.9 (1.52)	2.6 (1.50)	3.3 (1.69)	
Median	2.0	2.5	2.0	3.0	
Min, Max	2, 5	1, 6	1, 6	1, 7	
LS Mean (StdErr) [2]	2.87 (0.850)	3.46 (0.850)	2.65 (0.227)	3.34 (0.174)	
95% CI [2]	0.98, 4.77	1.57, 5.35	2.20, 3.09	3.00, 3.68	
Difference (95% CI) [2]		0.58 (-1.82, 2.99)		0.69 (0.19, 1.19)	
p-value [3]		0.600		0.007	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-thpy-a.sas Date: 15:50/07AUG2023

Table 35.2.7.1.8a
Summary of PGIC by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	62	118	
Mean (StdDev)	3.3 (1.50)	3.7 (1.83)	2.9 (1.63)	4.1 (1.71)	
Median	3.0	4.5	2.0	4.0	
Min, Max	2, 5	1, 6	1, 7	1, 7	
LS Mean (StdErr) [2]	3.33 (1.008)	4.01 (1.008)	2.77 (0.234)	3.92 (0.182)	
95% CI [2]	1.08, 5.57	1.76, 6.25	2.31, 3.23	3.56, 4.27	
Difference (95% CI) [2]		0.68 (-2.18, 3.54)		1.14 (0.62, 1.67)	
p-value [3]		0.608		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-thpy-a.sas Date: 15:50/07AUG2023

Table 35.2.7.1.8a
Summary of PGIC by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	119	
Mean (StdDev)	3.0 (1.73)	4.2 (1.86)	2.7 (1.74)	4.1 (1.73)	
Median	2.0	5.0	2.0	5.0	
Min, Max	2, 5	1, 6	1, 7	1, 7	
LS Mean (StdErr) [2]	3.88 (1.343)	4.44 (1.008)	2.52 (0.249)	3.92 (0.192)	
95% CI [2]	0.78, 6.97	2.11, 6.76	2.03, 3.01	3.55, 4.30	
Difference (95% CI) [2]		0.56 (-2.99, 4.11)		1.40 (0.85, 1.95)	
p-value [3]		0.724		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-thpy-a.sas Date: 15:50/07AUG2023

Table 35.2.7.1.8a
Summary of PGIC by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	116	
Mean (StdDev)	3.5 (2.38)	4.6 (2.00)	2.6 (1.66)	4.3 (1.72)	
Median	3.5	5.5	2.0	5.0	
Min, Max	1, 6	1, 6	1, 6	1, 7	
LS Mean (StdErr) [2]	3.40 (1.200)	3.94 (1.200)	2.56 (0.241)	4.22 (0.186)	
95% CI [2]	0.63, 6.17	1.17, 6.70	2.09, 3.04	3.85, 4.59	
Difference (95% CI) [2]		0.54 (-3.00, 4.08)		1.66 (1.12, 2.20)	
p-value [3]		0.735		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-thpy-a.sas Date: 15:50/07AUG2023

Table 35.2.7.1.8a
Summary of PGIC by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	119	
Mean (StdDev)	2.8 (2.22)	4.4 (2.13)	2.6 (1.68)	4.3 (1.81)	
Median	2.0	6.0	2.0	5.0	
Min, Max	1, 6	1, 6	1, 7	1, 7	
LS Mean (StdErr) [2]	2.70 (1.235)	3.96 (1.235)	2.49 (0.251)	4.16 (0.190)	
95% CI [2]	-0.09, 5.50	1.17, 6.76	1.99, 2.98	3.79, 4.54	
Difference (95% CI) [2]		1.26 (-2.30, 4.82)		1.68 (1.12, 2.24)	
p-value [3]		0.444		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-thpy-a.sas Date: 15:50/07AUG2023

Table 35.2.7.1.8a
Summary of PGIC by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patient Global Impression of Change

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	3.3 (2.22)	5.0 (1.31)	2.7 (1.86)	4.3 (1.73)	
Median	3.0	5.5	2.0	5.0	
Min, Max	1, 6	3, 6	1, 7	1, 7	
LS Mean (StdErr) [2]	2.88 (0.868)	4.12 (0.868)	2.71 (0.257)	4.21 (0.195)	
95% CI [2]	0.88, 4.89	2.11, 6.12	2.20, 3.21	3.82, 4.59	
Difference (95% CI) [2]		1.23 (-1.33, 3.79)		1.50 (0.93, 2.06)	
Hedges'G (95% CI)		0.50 (-0.76, 2.02)		0.72 (0.40, 1.05)	
p-value [3]		0.300		<0.0001	
					0.774

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-thpy-a.sas Date: 15:50/07AUG2023

Table 35.2.7.1.8a
Summary of PGIC by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	63	127	
Mean (StdDev)	4.5 (1.73)	4.1 (1.97)	4.5 (1.23)	4.2 (1.55)	
Median	5.0	4.5	5.0	4.0	
Min, Max	2, 6	1, 8	0, 8	0, 8	
LS Mean (StdErr) [2]	4.25 (1.073)	3.42 (1.073)	4.54 (0.202)	4.28 (0.155)	
95% CI [2]	1.86, 6.64	1.03, 5.81	4.14, 4.94	3.98, 4.59	
Difference (95% CI) [2]		-0.83 (-3.87, 2.21)		-0.25 (-0.70, 0.19)	
p-value [3]		0.557		0.261	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-thpy-a.sas Date: 15:50/07AUG2023

Table 35.2.7.1.8a
Summary of PGIC by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	62	117	
Mean (StdDev)	4.5 (1.29)	3.6 (1.43)	4.4 (1.40)	3.6 (1.62)	
Median	4.5	3.5	5.0	4.0	
Min, Max	3, 6	1, 5	1, 7	0, 9	
LS Mean (StdErr) [2]	4.75 (0.769)	3.92 (0.769)	4.46 (0.217)	3.67 (0.169)	
95% CI [2]	3.03, 6.46	2.20, 5.63	4.03, 4.89	3.34, 4.01	
Difference (95% CI) [2]		-0.83 (-3.01, 1.35)		-0.79 (-1.27, -0.30)	
p-value [3]		0.416		0.002	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-thpy-a.sas Date: 15:50/07AUG2023

Table 35.2.7.1.8a
Summary of PGIC by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	119	
Mean (StdDev)	4.7 (2.08)	3.8 (1.64)	4.7 (1.64)	3.7 (1.59)	
Median	4.0	3.0	5.0	4.0	
Min, Max	3, 7	2, 7	1, 8	0, 9	
LS Mean (StdErr) [2]	5.50 (1.275)	4.00 (0.956)	4.67 (0.234)	3.68 (0.180)	
95% CI [2]	2.56, 8.44	1.80, 6.20	4.21, 5.14	3.33, 4.04	
Difference (95% CI) [2]		-1.50 (-4.87, 1.87)		-0.99 (-1.51, -0.47)	
p-value [3]		0.334		<0.001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-thpy-a.sas Date: 15:50/07AUG2023

Table 35.2.7.1.8a
Summary of PGIC by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	116	
Mean (StdDev)	5.5 (0.58)	4.1 (1.55)	4.7 (1.45)	3.6 (1.68)	
Median	5.5	4.0	5.0	3.0	
Min, Max	5, 6	2, 7	2, 9	0, 9	
LS Mean (StdErr) [2]	5.45 (0.783)	4.22 (0.783)	4.79 (0.227)	3.63 (0.176)	
95% CI [2]	3.64, 7.25	2.41, 6.02	4.34, 5.23	3.28, 3.98	
Difference (95% CI) [2]		-1.23 (-3.54, 1.08)		-1.16 (-1.66, -0.65)	
p-value [3]		0.254		<0.0001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-thpy-a.sas Date: 15:50/07AUG2023

Table 35.2.7.1.8a
Summary of PGIC by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	119	
Mean (StdDev)	6.0 (0.82)	4.3 (2.12)	4.8 (1.59)	3.7 (1.80)	
Median	6.0	5.0	5.0	4.0	
Min, Max	5, 7	1, 8	0, 8	0, 9	
LS Mean (StdErr) [2]	5.50 (0.943)	3.83 (0.943)	4.77 (0.245)	3.69 (0.185)	
95% CI [2]	3.37, 7.64	1.70, 5.96	4.28, 5.25	3.32, 4.05	
Difference (95% CI) [2]		-1.67 (-4.40, 1.05)		-1.08 (-1.63, -0.53)	
p-value [3]		0.198		<0.001	

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-thpy-a.sas Date: 15:50/07AUG2023

Table 35.2.7.1.8a
Summary of PGIC by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Degree of Change	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	6.0 (0.82)	3.3 (1.67)	4.8 (1.56)	3.6 (1.83)	
Median	6.0	3.0	5.0	3.0	
Min, Max	5, 7	2, 7	1, 8	0, 9	
LS Mean (StdErr) [2]	5.72 (0.812)	2.95 (0.812)	4.76 (0.253)	3.59 (0.192)	
95% CI [2]	3.84, 7.59	1.08, 4.82	4.26, 5.26	3.21, 3.97	
Difference (95% CI) [2]		-2.77 (-5.17, -0.37)		-1.17 (-1.73, -0.62)	
Hedges'G (95% CI)		-1.21 (-3.01, -0.01)		-0.57 (-0.90, -0.26)	
p-value [3]		0.029		<0.0001	
					0.135

Abbreviations: PGIC = Patients' Global Impression of Change, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.2
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-sum-g-itt-thpy-a.sas Date: 15:50/07AUG2023

Table 35.2.7.3.1a
Proportion of Patients with PGIC at Least Moderately Better (PGIC >= 5) at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIC >= 5 at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	14/ 71 (19.7) (11.2, 30.9)	67/141 (47.5) (39.1, 56.1)	3.65 (1.78, 7.65) <0.001	2.40 (1.45, 3.95) <0.001	0.28 (0.15, 0.40) <0.0001	
Age Group (Years)						0.029
< 65	13/ 60 (21.7) (12.1, 34.2)	59/132 (44.7) (36.0, 53.6)	2.87 (1.35, 6.23) 0.003	2.04 (1.21, 3.43) 0.007	0.23 (0.09, 0.36) 0.001	
>= 65	1/ 11 (9.1) (0.2, 41.3)	8/ 9 (88.9) (51.8, 99.7)	32.00 (1.93, 1533.40) 0.002	11.33 (0.86, 149.12) 0.065	0.76 (0.41, 1.00) <0.0001	
Sex						0.285
Male	5/ 17 (29.4) (10.3, 56.0)	19/ 41 (46.3) (30.7, 62.6)	2.06 (0.56, 8.67) 0.231	1.59 (0.71, 3.57) 0.260	0.17 (-0.10, 0.45) 0.205	
Female	9/ 54 (16.7) (7.9, 29.3)	48/100 (48.0) (37.9, 58.2)	4.59 (1.93, 11.89) <0.001	2.91 (1.53, 5.54) 0.001	0.31 (0.17, 0.45) <0.0001	

Abbreviations: PGIC = Patients Global Impression of Change, CI = Confidence Interval
PGIC: 1=No change, 2=Almost the same, 3=A little Better, 4=Somewhat better, 5=Moderately better, 6=Better, 7=A great deal better
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-resp-itt-a.sas Date: 16:38/09AUG2023

Table 35.2.7.3.1a
Proportion of Patients with PGIC at Least Moderately Better (PGIC >= 5) at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIC >= 5 at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Region						0.855
North America	7/ 33 (21.2) (9.0, 38.9)	29/ 60 (48.3) (35.2, 61.6)	3.35 (1.12, 9.97) 0.017	2.21 (1.09, 4.47) 0.028	0.26 (0.07, 0.45) 0.008	
Europe	7/ 38 (18.4) (7.7, 34.3)	38/ 81 (46.9) (35.7, 58.3)	4.01 (1.47, 11.87) 0.003	2.56 (1.26, 5.18) 0.009	0.29 (0.12, 0.45) <0.001	
Country						NA
BEL	0/ 1 (0.0) (0.0, 97.5)	1/ 3 (33.3) (0.8, 90.6)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
CAN	1/ 5 (20.0) (0.5, 71.6)	6/ 8 (75.0) (34.9, 96.8)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
CHE	0/ 1 (0.0) (0.0, 97.5)	1/ 2 (50.0) (1.3, 98.7)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
DEU	5/ 15 (33.3) (11.8, 61.6)	5/ 19 (26.3) (9.1, 51.2)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	

Abbreviations: PGIC = Patients Global Impression of Change, CI = Confidence Interval
PGIC: 1=No change, 2=Almost the same, 3=A little Better, 4=Somewhat better, 5=Moderately better, 6=Better, 7=A great deal better
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-resp-itt-a.sas Date: 16:38/09AUG2023

Table 35.2.7.3.1a
Proportion of Patients with PGIC at Least Moderately Better (PGIC >= 5) at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIC >= 5 at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
DNK	0/0	1/ 1 (100.0) (2.5, 100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
ESP	0/ 3 (0.0) (0.0, 70.8)	7/ 14 (50.0) (23.0, 77.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
FRA	1/ 6 (16.7) (0.4, 64.1)	6/ 11 (54.5) (23.4, 83.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
GBR	0/ 5 (0.0) (0.0, 52.2)	6/ 11 (54.5) (23.4, 83.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
ITA	0/0	2/ 4 (50.0) (6.8, 93.2)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
NLD	0/ 3 (0.0) (0.0, 70.8)	5/ 9 (55.6) (21.2, 86.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
NOR	1/ 3 (33.3) (0.8, 90.6)	2/ 5 (40.0) (5.3, 85.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	

Abbreviations: PGIC = Patients Global Impression of Change, CI = Confidence Interval
PGIC: 1=No change, 2=Almost the same, 3=A little Better, 4=Somewhat better, 5=Moderately better, 6=Better, 7=A great deal better
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-resp-itt-a.sas Date: 16:38/09AUG2023

Table 35.2.7.3.1a
Proportion of Patients with PGIC at Least Moderately Better (PGIC >= 5) at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIC >= 5 at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
SWE	0/ 1 (0.0) (0.0, 97.5)	2/ 2 (100.0) (15.8, 100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
USA	6/ 28 (21.4) (8.3, 41.0)	23/ 52 (44.2) (30.5, 58.7)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
Baseline ISM Status						0.724
Moderate	5/ 26 (19.2) (6.6, 39.4)	26/ 52 (50.0) (35.8, 64.2)	4.23 (1.27, 16.41) 0.009	2.61 (1.14, 5.98) 0.023	0.31 (0.11, 0.52) 0.003	
Severe	9/ 45 (20.0) (9.6, 34.6)	40/ 87 (46.0) (35.2, 57.0)	3.35 (1.35, 8.73) 0.004	2.27 (1.21, 4.26) 0.010	0.26 (0.10, 0.41) 0.001	
Baseline Serum Tryptase (ng/mL)						0.584
< 20	3/ 15 (20.0) (4.3, 48.1)	11/ 28 (39.3) (21.5, 59.4)	2.49 (0.48, 16.26) 0.231	1.91 (0.63, 5.80) 0.254	0.18 (-0.09, 0.46) 0.190	
>= 20	11/ 56 (19.6) (10.2, 32.4)	56/113 (49.6) (40.0, 59.1)	4.02 (1.79, 9.40) <0.001	2.52 (1.44, 4.43) 0.001	0.30 (0.16, 0.44) <0.0001	

Abbreviations: PGIC = Patients Global Impression of Change, CI = Confidence Interval
PGIC: 1=No change, 2=Almost the same, 3=A little Better, 4=Somewhat better, 5=Moderately better, 6=Better, 7=A great deal better
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-resp-itt-a.sas Date: 16:38/09AUG2023

Table 35.2.7.3.1a
Proportion of Patients with PGIC at Least Moderately Better (PGIC >= 5) at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIC >= 5 at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.441
0 or 1	13/ 67 (19.4) (10.8, 30.9)	64/131 (48.9) (40.0, 57.7)	3.94 (1.87, 8.49) <0.0001	2.51 (1.49, 4.21) <0.001	0.29 (0.16, 0.42) <0.0001	
2+	1/ 4 (25.0) (0.6, 80.6)	3/ 10 (30.0) (6.7, 65.2)	1.30 (0.06, 85.10) 0.851	1.20 (0.20, 7.07) 0.840	0.06 (-0.49, 0.60) 0.842	
Prior TKI therapy						0.841
Yes	1/ 4 (25.0) (0.6, 80.6)	6/ 10 (60.0) (26.2, 87.8)	2.88 (0.12, 163.73) 0.448	2.88 (0.09, 90.81) 0.549	0.28 (-0.36, 0.93) 0.391	
No	13/ 67 (19.4) (10.8, 30.9)	61/131 (46.6) (37.8, 55.5)	3.55 (1.70, 7.70) <0.001	2.39 (1.41, 4.03) 0.001	0.27 (0.14, 0.40) <0.0001	

Abbreviations: PGIC = Patients Global Impression of Change, CI = Confidence Interval
PGIC: 1=No change, 2=Almost the same, 3=A little Better, 4=Somewhat better, 5=Moderately better, 6=Better, 7=A great deal better
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgic-resp-itt-a.sas Date: 16:38/09AUG2023

Table 35.2.7.3.3a
Proportion of Patients with PGIC Degree of Change <=1.5 at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIC Degree of Change <= 1.5 at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	1/ 71 (1.4) (0.0, 7.6)	11/141 (7.8) (4.0, 13.5)	5.81 (0.78, 245.14) 0.069	5.81 (0.64, 53.03) 0.119	0.06 (0.01, 0.11) 0.021	
Age Group (Years)						0.971
< 65	1/ 60 (1.7) (0.0, 8.9)	9/132 (6.8) (3.2, 12.5)	4.43 (0.57, 191.57) 0.139	4.43 (0.49, 40.30) 0.186	0.05 (-0.00, 0.11) 0.060	
>= 65	0/ 11 (0.0) (0.0, 28.5)	2/ 9 (22.2) (2.8, 60.0)	NE (0.14, NE) 0.285	NE (NE, NE) NE	0.16 (-0.10, 0.43) 0.232	
Sex						0.982
Male	0/ 17 (0.0) (0.0, 19.5)	1/ 41 (2.4) (0.1, 12.9)	NE (0.02, NE) 0.508	NE (NE, NE) NE	0.03 (-0.02, 0.07) 0.303	
Female	1/ 54 (1.9) (0.0, 9.9)	10/100 (10.0) (4.9, 17.6)	5.59 (0.72, 238.49) 0.079	5.59 (0.59, 52.99) 0.134	0.08 (0.01, 0.14) 0.030	

Abbreviations: PGIC = Patients Global Impression of Change, CI = Confidence Interval
PGIC: 1=No change, 2=Almost the same, 3=A little Better, 4=Somewhat better, 5=Moderately better, 6=Better, 7=A great deal better
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgicdc-resp-itt-a.sas Date: 11:52/10AUG2023

Table 35.2.7.3.3a
Proportion of Patients with PGIC Degree of Change <=1.5 at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIC Degree of Change <= 1.5 at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Region						0.976
North America	1/ 33 (3.0) (0.1, 15.8)	2/ 60 (3.3) (0.4, 11.5)	1.23 (0.05, 79.34) 0.896	1.23 (0.05, 29.52) 0.896	0.01 (-0.06, 0.07) 0.881	
Europe	0/ 38 (0.0) (0.0, 9.3)	9/ 81 (11.1) (5.2, 20.0)	NE (1.27, NE) 0.033	NE (NE, NE) NE	0.11 (0.04, 0.18) 0.002	
Country						NA
BEL	0/ 1 (0.0) (0.0, 97.5)	0/ 3 (0.0) (0.0, 70.8)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
CAN	0/ 5 (0.0) (0.0, 52.2)	1/ 8 (12.5) (0.3, 52.7)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
CHE	0/ 1 (0.0) (0.0, 97.5)	0/ 2 (0.0) (0.0, 84.2)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
DEU	0/ 15 (0.0) (0.0, 21.8)	1/ 19 (5.3) (0.1, 26.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	

Abbreviations: PGIC = Patients Global Impression of Change, CI = Confidence Interval
PGIC: 1=No change, 2=Almost the same, 3=A little Better, 4=Somewhat better, 5=Moderately better, 6=Better, 7=A great deal better
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgicdc-resp-itt-a.sas Date: 11:52/10AUG2023

Table 35.2.7.3.3a
Proportion of Patients with PGIC Degree of Change <=1.5 at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIC Degree of Change <= 1.5 at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
DNK	0/0	1/ 1 (100.0) (2.5, 100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
ESP	0/ 3 (0.0) (0.0, 70.8)	1/ 14 (7.1) (0.2, 33.9)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
FRA	0/ 6 (0.0) (0.0, 45.9)	3/ 11 (27.3) (6.0, 61.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
GBR	0/ 5 (0.0) (0.0, 52.2)	2/ 11 (18.2) (2.3, 51.8)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
ITA	0/0	0/ 4 (0.0) (0.0, 60.2)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
NLD	0/ 3 (0.0) (0.0, 70.8)	1/ 9 (11.1) (0.3, 48.2)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
NOR	0/ 3 (0.0) (0.0, 70.8)	0/ 5 (0.0) (0.0, 52.2)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	

Abbreviations: PGIC = Patients Global Impression of Change, CI = Confidence Interval
PGIC: 1=No change, 2=Almost the same, 3=A little Better, 4=Somewhat better, 5=Moderately better, 6=Better, 7=A great deal better
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgicdc-resp-itt-a.sas Date: 11:52/10AUG2023

Table 35.2.7.3.3a
Proportion of Patients with PGIC Degree of Change <=1.5 at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIC Degree of Change <= 1.5 at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
SWE	0/ 1 (0.0) (0.0, 97.5)	0/ 2 (0.0) (0.0, 84.2)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
USA	1/ 28 (3.6) (0.1, 18.3)	1/ 52 (1.9) (0.0, 10.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
Baseline ISM Status						0.975
Moderate	0/ 26 (0.0) (0.0, 13.2)	3/ 52 (5.8) (1.2, 15.9)	NE (0.23, NE) 0.261	NE (NE, NE) NE	0.05 (-0.01, 0.11) 0.103	
Severe	1/ 45 (2.2) (0.1, 11.8)	8/ 87 (9.2) (4.1, 17.3)	4.37 (0.54, 194.67) 0.145	4.37 (0.47, 40.79) 0.195	0.07 (-0.01, 0.14) 0.073	
Baseline Serum Tryptase (ng/mL)						0.972
< 20	1/ 15 (6.7) (0.2, 31.9)	2/ 28 (7.1) (0.9, 23.5)	0.84 (0.04, 55.59) 0.904	0.84 (0.05, 14.25) >0.999	-0.01 (-0.16, 0.14) 0.901	
>= 20	0/ 56 (0.0) (0.0, 6.4)	9/113 (8.0) (3.7, 14.6)	NE (1.30, NE) 0.031	NE (NE, NE) NE	0.08 (0.03, 0.13) 0.002	

Abbreviations: PGIC = Patients Global Impression of Change, CI = Confidence Interval
PGIC: 1=No change, 2=Almost the same, 3=A little Better, 4=Somewhat better, 5=Moderately better, 6=Better, 7=A great deal better
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgicdc-resp-itt-a.sas Date: 11:52/10AUG2023

Table 35.2.7.3.3a
Proportion of Patients with PGIC Degree of Change <=1.5 at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIC Degree of Change <= 1.5 at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.977
0 or 1	1/ 67 (1.5) (0.0, 8.0)	10/131 (7.6) (3.7, 13.6)	5.48 (0.70, 228.67) 0.087	5.48 (0.58, 51.77) 0.138	0.06 (0.01, 0.11) 0.031	
2+	0/ 4 (0.0) (0.0, 60.2)	1/ 10 (10.0) (0.3, 44.5)	NE (0.02, NE) 0.564	NE (NE, NE) NE	0.09 (-0.10, 0.29) 0.356	
Prior TKI therapy						0.995
Yes	0/ 4 (0.0) (0.0, 60.2)	0/ 10 (0.0) (0.0, 30.8)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
No	1/ 67 (1.5) (0.0, 8.0)	11/131 (8.4) (4.3, 14.5)	6.10 (0.82, 259.78) 0.059	6.10 (0.67, 55.57) 0.108	0.07 (0.01, 0.12) 0.017	

Abbreviations: PGIC = Patients Global Impression of Change, CI = Confidence Interval
PGIC: 1=No change, 2=Almost the same, 3=A little Better, 4=Somewhat better, 5=Moderately better, 6=Better, 7=A great deal better
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgicdc-resp-itt-a.sas Date: 11:52/10AUG2023

Table 35.2.6.1.1a
Summary of PGIS by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	2.7 (0.91)	2.7 (0.91)	2.9 (1.04)	2.4 (0.53)	
Median	3.0	3.0	3.0	2.0	
Min, Max	1, 4	1, 4	1, 4	2, 3	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-age-a.sas Date: 15:46/07AUG2023

Table 35.2.6.1.1a
Summary of PGIS by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	2.2 (0.71)	2.1 (0.89)	2.6 (0.92)	1.9 (0.78)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	1, 4	1, 3	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	-0.33 (0.144)	-0.50 (0.103)	-0.30 (0.495)	-0.94 (0.627)	
95% CI [2]	-0.61, -0.04	-0.71, -0.30	-1.35, 0.74	-2.27, 0.39	
Difference (95% CI) in CFB [2]		-0.18 (-0.49, 0.14)		-0.63 (-1.61, 0.34)	
p-value [3]		0.269		0.188	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-age-a.sas Date: 15:46/07AUG2023

Table 35.2.6.1.1a
Summary of PGIS by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	119	10	9	
Mean (StdDev)	2.3 (0.83)	1.9 (0.83)	2.8 (0.79)	1.6 (0.73)	
Median	2.0	2.0	3.0	1.0	
Min, Max	1, 4	0, 4	2, 4	1, 3	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-0.26 (0.160)	-0.70 (0.114)	-0.06 (0.524)	-1.06 (0.659)	
95% CI [2]	-0.57, 0.06	-0.93, -0.48	-1.17, 1.06	-2.46, 0.35	
Difference (95% CI) in CFB [2]		-0.45 (-0.80, -0.10)		-1.00 (-2.05, 0.05)	
p-value [3]		0.012		0.060	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-age-a.sas Date: 15:46/07AUG2023

Table 35.2.6.1.1a
Summary of PGIS by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	119	7	9	
Mean (StdDev)	2.3 (0.84)	1.9 (0.80)	2.9 (1.07)	1.2 (0.67)	
Median	2.0	2.0	3.0	1.0	
Min, Max	1, 4	0, 4	1, 4	0, 2	
C4D1 CFB					
n	50	115	7	9	
LS Mean (StdErr) [2]	-0.30 (0.162)	-0.70 (0.115)	-0.10 (0.502)	-1.24 (0.670)	
95% CI [2]	-0.62, 0.02	-0.92, -0.47	-1.19, 1.00	-2.70, 0.22	
Difference (95% CI) in CFB [2]		-0.40 (-0.74, -0.05)		-1.14 (-2.37, 0.08)	
p-value [3]		0.024		0.064	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-age-a.sas Date: 15:46/07AUG2023

Table 35.2.6.1.1a
Summary of PGIS by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	117	9	8	
Mean (StdDev)	2.2 (0.90)	1.9 (0.77)	2.9 (0.78)	1.3 (1.04)	
Median	2.0	2.0	3.0	1.0	
Min, Max	0, 4	0, 4	2, 4	0, 3	
C5D1 CFB					
n	53	111	9	8	
LS Mean (StdErr) [2]	-0.38 (0.160)	-0.75 (0.117)	0.06 (0.600)	-1.31 (0.778)	
95% CI [2]	-0.70, -0.07	-0.98, -0.52	-1.23, 1.36	-2.99, 0.37	
Difference (95% CI) in CFB [2]		-0.37 (-0.72, -0.02)		-1.38 (-2.68, -0.07)	
p-value [3]		0.037		0.041	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-age-a.sas Date: 15:46/07AUG2023

Table 35.2.6.1.1a
Summary of PGIS by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	2.2 (0.80)	1.9 (0.88)	2.8 (1.04)	1.1 (0.60)	
Median	2.0	2.0	3.0	1.0	
Min, Max	1, 4	0, 4	1, 4	0, 2	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-0.30 (0.158)	-0.66 (0.113)	-0.08 (0.442)	-1.29 (0.595)	
95% CI [2]	-0.61, 0.02	-0.88, -0.43	-1.03, 0.88	-2.58, -0.01	
Difference (95% CI) in CFB [2]		-0.36 (-0.70, -0.02)		-1.22 (-2.27, -0.16)	
p-value [3]		0.040		0.027	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-age-a.sas Date: 15:46/07AUG2023

Table 35.2.6.1.1a
Summary of PGIS by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	2.2 (0.86)	1.9 (0.90)	2.7 (0.95)	1.6 (1.06)	
Median	2.0	2.0	3.0	1.5	
Min, Max	1, 4	0, 4	1, 4	0, 3	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-0.28 (0.165)	-0.65 (0.116)	-0.08 (0.565)	-0.92 (0.748)	
95% CI [2]	-0.60, 0.05	-0.88, -0.42	-1.30, 1.13	-2.52, 0.69	
Difference (95% CI) in CFB [2]		-0.37 (-0.72, -0.02)		-0.83 (-2.05, 0.38)	
Hedges'G (95% CI) in CFB		-0.30 (-0.65, 0.03)		-0.41 (-1.49, 0.55)	
p-value [3]		0.039		0.163	
					0.535

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-age-a.sas Date: 15:46/07AUG2023

Table 35.2.6.1.2a
Summary of PGIS by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	2.4 (0.96)	2.4 (0.86)	2.8 (0.90)	2.8 (0.89)	
Median	2.5	2.0	3.0	3.0	
Min, Max	1, 4	1, 4	1, 4	1, 4	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-sex-a.sas Date: 15:46/07AUG2023

Table 35.2.6.1.2a
Summary of PGIS by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	2.2 (0.83)	2.1 (0.90)	2.3 (0.73)	2.1 (0.88)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	1, 4	1, 4	0, 4	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	-0.01 (0.238)	-0.23 (0.160)	-0.41 (0.157)	-0.63 (0.127)	
95% CI [2]	-0.49, 0.47	-0.55, 0.09	-0.72, -0.10	-0.88, -0.37	
Difference (95% CI) in CFB [2]		-0.22 (-0.75, 0.31)		-0.21 (-0.55, 0.13)	
p-value [3]		0.408		0.221	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-sex-a.sas Date: 15:46/07AUG2023

Table 35.2.6.1.2a
Summary of PGIS by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	94	
Mean (StdDev)	2.1 (0.86)	2.0 (0.67)	2.5 (0.81)	1.9 (0.88)	
Median	2.0	2.0	2.5	2.0	
Min, Max	1, 4	1, 3	1, 4	0, 4	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-0.25 (0.226)	-0.44 (0.162)	-0.17 (0.180)	-0.78 (0.141)	
95% CI [2]	-0.71, 0.20	-0.77, -0.11	-0.52, 0.19	-1.06, -0.50	
Difference (95% CI) in CFB [2]		-0.18 (-0.70, 0.33)		-0.61 (-1.00, -0.22)	
p-value [3]		0.471		0.002	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-sex-a.sas Date: 15:46/07AUG2023

Table 35.2.6.1.2a
Summary of PGIS by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	92	
Mean (StdDev)	2.3 (0.96)	1.9 (0.68)	2.4 (0.86)	1.9 (0.86)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	1, 4	1, 4	0, 4	
C4D1 CFB					
n	14	34	43	90	
LS Mean (StdErr) [2]	-0.05 (0.287)	-0.46 (0.202)	-0.30 (0.171)	-0.77 (0.131)	
95% CI [2]	-0.63, 0.53	-0.87, -0.06	-0.64, 0.04	-1.03, -0.52	
Difference (95% CI) in CFB [2]		-0.42 (-1.06, 0.23)		-0.47 (-0.84, -0.11)	
p-value [3]		0.198		0.011	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-sex-a.sas Date: 15:46/07AUG2023

Table 35.2.6.1.2a
Summary of PGIS by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	89	
Mean (StdDev)	2.1 (0.99)	1.8 (0.73)	2.3 (0.89)	1.9 (0.82)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	1, 4	1, 4	0, 4	
C5D1 CFB					
n	16	32	46	87	
LS Mean (StdErr) [2]	-0.07 (0.239)	-0.51 (0.177)	-0.34 (0.181)	-0.83 (0.142)	
95% CI [2]	-0.55, 0.41	-0.87, -0.16	-0.70, 0.01	-1.12, -0.55	
Difference (95% CI) in CFB [2]		-0.44 (-0.98, 0.09)		-0.49 (-0.88, -0.10)	
p-value [3]		0.104		0.015	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-sex-a.sas Date: 15:46/07AUG2023

Table 35.2.6.1.2a
Summary of PGIS by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	2.4 (0.91)	1.7 (0.77)	2.3 (0.83)	1.9 (0.92)	
Median	3.0	2.0	2.0	2.0	
Min, Max	1, 4	1, 4	1, 4	0, 4	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	0.18 (0.287)	-0.49 (0.195)	-0.38 (0.166)	-0.74 (0.130)	
95% CI [2]	-0.39, 0.76	-0.88, -0.10	-0.70, -0.05	-1.00, -0.48	
Difference (95% CI) in CFB [2]		-0.67 (-1.32, -0.03)		-0.37 (-0.73, -0.00)	
p-value [3]		0.040		0.047	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-sex-a.sas Date: 15:46/07AUG2023

Table 35.2.6.1.2a
Summary of PGIS by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	2.3 (0.95)	1.8 (0.89)	2.2 (0.87)	1.9 (0.92)	
Median	2.5	2.0	2.0	2.0	
Min, Max	1, 4	1, 4	1, 4	0, 4	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	0.16 (0.267)	-0.38 (0.186)	-0.37 (0.181)	-0.77 (0.141)	
95% CI [2]	-0.38, 0.70	-0.76, -0.01	-0.73, -0.01	-1.05, -0.49	
Difference (95% CI) in CFB [2]		-0.54 (-1.14, 0.05)		-0.40 (-0.79, -0.02)	
Hedges'G (95% CI) in CFB		-0.50 (-1.16, 0.11)		-0.31 (-0.68, 0.05)	
p-value [3]		0.074		0.040	
					0.710

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-sex-a.sas Date: 15:46/07AUG2023

Table 35.2.6.1.3a
Summary of PGIS by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	2.6 (0.93)	2.5 (0.92)	2.8 (0.92)	2.8 (0.85)	
Median	2.5	2.0	3.0	3.0	
Min, Max	1, 4	1, 4	1, 4	1, 4	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-reg-a.sas Date: 15:46/07AUG2023

Table 35.2.6.1.3a
Summary of PGIS by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	2.2 (0.78)	2.0 (0.91)	2.4 (0.72)	2.2 (0.86)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	1, 4	1, 4	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	-0.30 (0.208)	-0.47 (0.163)	-0.33 (0.174)	-0.54 (0.132)	
95% CI [2]	-0.71, 0.12	-0.80, -0.15	-0.68, 0.01	-0.80, -0.28	
Difference (95% CI) in CFB [2]		-0.17 (-0.63, 0.28)		-0.20 (-0.59, 0.18)	
p-value [3]		0.449		0.293	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-reg-a.sas Date: 15:46/07AUG2023

Table 35.2.6.1.3a
Summary of PGIS by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	52	37	76	
Mean (StdDev)	2.2 (0.77)	1.8 (0.76)	2.5 (0.87)	2.0 (0.87)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	1, 4	0, 4	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	-0.21 (0.209)	-0.63 (0.165)	-0.20 (0.200)	-0.77 (0.148)	
95% CI [2]	-0.63, 0.20	-0.96, -0.30	-0.60, 0.19	-1.07, -0.48	
Difference (95% CI) in CFB [2]		-0.42 (-0.88, 0.04)		-0.57 (-1.01, -0.13)	
p-value [3]		0.074		0.012	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-reg-a.sas Date: 15:46/07AUG2023

Table 35.2.6.1.3a
Summary of PGIS by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	51	37	77	
Mean (StdDev)	2.2 (0.83)	1.8 (0.68)	2.4 (0.90)	2.0 (0.88)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	1, 4	1, 4	0, 4	
C4D1 CFB					
n	20	48	37	76	
LS Mean (StdErr) [2]	-0.16 (0.241)	-0.57 (0.180)	-0.32 (0.190)	-0.81 (0.142)	
95% CI [2]	-0.64, 0.32	-0.92, -0.21	-0.69, 0.06	-1.09, -0.52	
Difference (95% CI) in CFB [2]		-0.41 (-0.91, 0.09)		-0.49 (-0.91, -0.07)	
p-value [3]		0.107		0.022	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-reg-a.sas Date: 15:46/07AUG2023

Table 35.2.6.1.3a
Summary of PGIS by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	37	78	
Mean (StdDev)	2.0 (0.94)	1.8 (0.69)	2.4 (0.87)	1.9 (0.86)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	42	37	77	
LS Mean (StdErr) [2]	-0.31 (0.227)	-0.61 (0.186)	-0.28 (0.198)	-0.85 (0.147)	
95% CI [2]	-0.77, 0.14	-0.98, -0.24	-0.67, 0.11	-1.14, -0.56	
Difference (95% CI) in CFB [2]		-0.30 (-0.79, 0.20)		-0.57 (-1.01, -0.14)	
p-value [3]		0.238		0.010	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-reg-a.sas Date: 15:46/07AUG2023

Table 35.2.6.1.3a
Summary of PGIS by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	2.2 (0.93)	1.7 (0.67)	2.4 (0.79)	2.0 (0.99)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	1, 3	1, 4	0, 4	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	-0.03 (0.215)	-0.60 (0.165)	-0.39 (0.193)	-0.73 (0.143)	
95% CI [2]	-0.46, 0.39	-0.93, -0.27	-0.77, -0.01	-1.01, -0.45	
Difference (95% CI) in CFB [2]		-0.56 (-1.03, -0.09)		-0.34 (-0.77, 0.09)	
p-value [3]		0.019		0.116	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-reg-a.sas Date: 15:46/07AUG2023

Table 35.2.6.1.3a
Summary of PGIS by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	2.1 (0.95)	1.6 (0.81)	2.4 (0.83)	2.0 (0.94)	
Median	2.0	1.0	2.0	2.0	
Min, Max	1, 4	0, 4	1, 4	0, 4	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-0.06 (0.247)	-0.64 (0.193)	-0.31 (0.194)	-0.65 (0.144)	
95% CI [2]	-0.55, 0.44	-1.03, -0.25	-0.70, 0.07	-0.93, -0.37	
Difference (95% CI) in CFB [2]		-0.58 (-1.10, -0.07)		-0.34 (-0.76, 0.09)	
Hedges'G (95% CI) in CFB		-0.46 (-0.99, 0.05)		-0.27 (-0.68, 0.12)	
p-value [3]		0.027		0.122	
					0.486

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-reg-a.sas Date: 15:46/07AUG2023

Table 35.2.6.1.4a
Summary of PGIS by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-cou-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.4a
Summary of PGIS by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-cou-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.4a
Summary of PGIS by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-cou-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.4a
Summary of PGIS by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-cou-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.4a
Summary of PGIS by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-cou-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.5a
Summary of PGIS by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	2.6 (1.10)	2.4 (0.84)	2.8 (0.82)	2.8 (0.89)	
Median	2.5	2.0	3.0	3.0	
Min, Max	1, 4	1, 4	1, 4	1, 4	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-ism-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.5a
Summary of PGIS by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	2.1 (0.78)	1.8 (0.76)	2.4 (0.73)	2.3 (0.91)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	1, 4	1, 4	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	-0.12 (0.207)	-0.45 (0.141)	-0.37 (0.167)	-0.54 (0.134)	
95% CI [2]	-0.54, 0.29	-0.73, -0.17	-0.70, -0.04	-0.80, -0.27	
Difference (95% CI) in CFB [2]		-0.33 (-0.76, 0.11)		-0.16 (-0.55, 0.22)	
p-value [3]		0.139		0.400	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-ism-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.5a
Summary of PGIS by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	78	
Mean (StdDev)	2.4 (0.85)	1.7 (0.66)	2.4 (0.84)	2.1 (0.89)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 3	1, 4	0, 4	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	0.03 (0.230)	-0.63 (0.151)	-0.34 (0.181)	-0.78 (0.149)	
95% CI [2]	-0.43, 0.48	-0.93, -0.33	-0.69, 0.02	-1.08, -0.49	
Difference (95% CI) in CFB [2]		-0.65 (-1.14, -0.17)		-0.45 (-0.87, -0.03)	
p-value [3]		0.009		0.037	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-ism-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.5a
Summary of PGIS by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	80	
Mean (StdDev)	2.1 (1.01)	1.7 (0.66)	2.4 (0.79)	2.0 (0.88)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 3	1, 4	0, 4	
C4D1 CFB					
n	19	44	38	79	
LS Mean (StdErr) [2]	-0.13 (0.220)	-0.57 (0.150)	-0.34 (0.191)	-0.82 (0.147)	
95% CI [2]	-0.57, 0.31	-0.87, -0.27	-0.72, 0.04	-1.11, -0.53	
Difference (95% CI) in CFB [2]		-0.44 (-0.90, 0.02)		-0.48 (-0.91, -0.05)	
p-value [3]		0.059		0.029	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-ism-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.5a
Summary of PGIS by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	41	78	
Mean (StdDev)	2.0 (1.02)	1.7 (0.69)	2.4 (0.83)	1.9 (0.86)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	1, 3	1, 4	0, 4	
C5D1 CFB					
n	21	42	41	76	
LS Mean (StdErr) [2]	-0.19 (0.226)	-0.54 (0.160)	-0.36 (0.188)	-0.93 (0.149)	
95% CI [2]	-0.64, 0.27	-0.86, -0.22	-0.73, 0.01	-1.22, -0.63	
Difference (95% CI) in CFB [2]		-0.36 (-0.83, 0.12)		-0.57 (-1.00, -0.13)	
p-value [3]		0.139		0.011	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-ism-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.5a
Summary of PGIS by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	2.1 (0.97)	1.7 (0.66)	2.4 (0.75)	2.0 (0.98)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 3	1, 4	0, 4	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	-0.04 (0.209)	-0.53 (0.143)	-0.35 (0.188)	-0.79 (0.146)	
95% CI [2]	-0.45, 0.38	-0.82, -0.25	-0.72, 0.03	-1.07, -0.50	
Difference (95% CI) in CFB [2]		-0.49 (-0.93, -0.05)		-0.44 (-0.87, -0.01)	
p-value [3]		0.028		0.047	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-ism-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.5a
Summary of PGIS by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	2.0 (0.93)	1.8 (0.91)	2.4 (0.84)	1.9 (0.91)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	1, 4	0, 4	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	-0.19 (0.233)	-0.43 (0.160)	-0.25 (0.189)	-0.80 (0.149)	
95% CI [2]	-0.65, 0.28	-0.75, -0.11	-0.62, 0.12	-1.09, -0.50	
Difference (95% CI) in CFB [2]		-0.24 (-0.73, 0.24)		-0.55 (-0.98, -0.12)	
Hedges'G (95% CI) in CFB		-0.23 (-0.77, 0.30)		-0.43 (-0.83, -0.05)	
p-value [3]		0.317		0.013	
					0.335

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-ism-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.6a
Summary of PGIS by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	2.8 (0.93)	2.4 (0.93)	2.7 (0.93)	2.8 (0.88)	
Median	3.0	2.0	3.0	3.0	
Min, Max	1, 4	1, 4	1, 4	1, 4	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-tryp-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.6a
Summary of PGIS by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	2.1 (0.74)	2.3 (0.90)	2.4 (0.76)	2.1 (0.88)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	1, 4	1, 4	0, 4	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	-0.44 (0.289)	-0.17 (0.189)	-0.37 (0.133)	-0.71 (0.097)	
95% CI [2]	-1.03, 0.14	-0.55, 0.21	-0.64, -0.11	-0.90, -0.51	
Difference (95% CI) in CFB [2]		0.27 (-0.41, 0.95)		-0.33 (-0.65, -0.01)	
p-value [3]		0.422		0.042	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-tryp-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.6a
Summary of PGIS by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	102	
Mean (StdDev)	2.2 (0.77)	2.0 (0.66)	2.5 (0.85)	1.9 (0.87)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 3	1, 4	1, 4	0, 4	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	-0.46 (0.243)	-0.41 (0.159)	-0.23 (0.156)	-0.88 (0.113)	
95% CI [2]	-0.96, 0.03	-0.73, -0.08	-0.53, 0.08	-1.10, -0.66	
Difference (95% CI) in CFB [2]		0.06 (-0.52, 0.63)		-0.65 (-1.03, -0.28)	
p-value [3]		0.840		<0.001	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-tryp-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.6a
Summary of PGIS by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	104	
Mean (StdDev)	2.2 (0.73)	2.1 (0.68)	2.4 (0.92)	1.8 (0.83)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 3	1, 4	1, 4	0, 4	
C4D1 CFB					
n	11	24	46	100	
LS Mean (StdErr) [2]	-0.34 (0.301)	-0.37 (0.194)	-0.37 (0.153)	-0.93 (0.107)	
95% CI [2]	-0.95, 0.27	-0.77, 0.03	-0.67, -0.06	-1.15, -0.72	
Difference (95% CI) in CFB [2]		-0.03 (-0.73, 0.67)		-0.57 (-0.93, -0.21)	
p-value [3]		0.925		0.002	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-tryp-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.6a
Summary of PGIS by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	99	
Mean (StdDev)	2.1 (0.73)	2.0 (0.82)	2.3 (0.96)	1.8 (0.79)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	12	25	50	94	
LS Mean (StdErr) [2]	-0.43 (0.311)	-0.41 (0.205)	-0.35 (0.152)	-0.97 (0.113)	
95% CI [2]	-1.06, 0.21	-0.83, 0.00	-0.65, -0.05	-1.19, -0.75	
Difference (95% CI) in CFB [2]		0.01 (-0.71, 0.74)		-0.62 (-0.98, -0.25)	
p-value [3]		0.972		0.001	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-tryp-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.6a
Summary of PGIS by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	2.1 (0.62)	2.1 (0.87)	2.4 (0.89)	1.8 (0.88)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 3	1, 4	1, 4	0, 4	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-0.45 (0.355)	-0.26 (0.228)	-0.31 (0.141)	-0.93 (0.102)	
95% CI [2]	-1.16, 0.27	-0.72, 0.20	-0.59, -0.04	-1.13, -0.73	
Difference (95% CI) in CFB [2]		0.19 (-0.64, 1.01)		-0.62 (-0.95, -0.28)	
p-value [3]		0.651		<0.001	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-tryp-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.6a
Summary of PGIS by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	2.1 (0.64)	2.2 (0.94)	2.3 (0.94)	1.8 (0.89)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 3	1, 4	1, 4	0, 4	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	-0.32 (0.343)	-0.20 (0.222)	-0.37 (0.148)	-0.94 (0.107)	
95% CI [2]	-1.01, 0.38	-0.65, 0.26	-0.66, -0.07	-1.15, -0.72	
Difference (95% CI) in CFB [2]		0.12 (-0.68, 0.92)		-0.57 (-0.93, -0.21)	
Hedges'G (95% CI) in CFB		0.11 (-0.63, 0.86)		-0.54 (-0.90, -0.20)	
p-value [3]		0.761		0.002	
					0.071

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-tryp-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.7a
Summary of PGIS by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	2.7 (0.92)	2.7 (0.90)	3.3 (0.96)	3.0 (0.82)	
Median	3.0	3.0	3.5	3.0	
Min, Max	1, 4	1, 4	2, 4	2, 4	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-ecog-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.7a
Summary of PGIS by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	2.3 (0.76)	2.1 (0.89)	2.5 (0.58)	2.2 (0.83)	
Median	2.0	2.0	2.5	2.0	
Min, Max	1, 4	0, 4	2, 3	1, 4	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	-0.30 (0.138)	-0.50 (0.106)	-0.83 (0.605)	-0.79 (0.460)	
95% CI [2]	-0.57, -0.03	-0.71, -0.29	-2.19, 0.54	-1.84, 0.25	
Difference (95% CI) in CFB [2]		-0.20 (-0.50, 0.10)		0.03 (-1.11, 1.18)	
p-value [3]		0.194		0.950	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-ecog-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.7a
Summary of PGIS by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	119	4	9	
Mean (StdDev)	2.4 (0.83)	1.9 (0.80)	2.5 (1.00)	2.4 (1.01)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	2, 4	1, 4	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-0.17 (0.149)	-0.73 (0.113)	-1.00 (0.944)	-0.75 (0.719)	
95% CI [2]	-0.47, 0.12	-0.95, -0.51	-3.13, 1.13	-2.38, 0.88	
Difference (95% CI) in CFB [2]		-0.55 (-0.88, -0.23)		0.25 (-1.54, 2.04)	
p-value [3]		0.001		0.759	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-ecog-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.7a
Summary of PGIS by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	118	4	10	
Mean (StdDev)	2.3 (0.89)	1.8 (0.79)	2.8 (0.50)	2.4 (0.84)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	2, 3	1, 4	
C4D1 CFB					
n	53	114	4	10	
LS Mean (StdErr) [2]	-0.26 (0.154)	-0.75 (0.114)	-0.11 (0.825)	-0.22 (0.631)	
95% CI [2]	-0.57, 0.04	-0.97, -0.52	-1.95, 1.73	-1.63, 1.18	
Difference (95% CI) in CFB [2]		-0.48 (-0.82, -0.15)		-0.11 (-1.64, 1.42)	
p-value [3]		0.005		0.874	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-ecog-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.7a
Summary of PGIS by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	115	4	10	
Mean (StdDev)	2.3 (0.93)	1.8 (0.76)	2.5 (0.58)	2.2 (1.14)	
Median	2.0	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	2, 3	0, 4	
C5D1 CFB					
n	58	109	4	10	
LS Mean (StdErr) [2]	-0.25 (0.151)	-0.76 (0.116)	-1.91 (0.883)	-1.65 (0.676)	
95% CI [2]	-0.55, 0.04	-0.99, -0.53	-3.87, 0.06	-3.15, -0.14	
Difference (95% CI) in CFB [2]		-0.51 (-0.84, -0.18)		0.26 (-1.37, 1.89)	
p-value [3]		0.003		0.731	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-ecog-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.7a
Summary of PGIS by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	2.3 (0.83)	1.8 (0.85)	3.0 (0.82)	2.6 (0.97)	
Median	2.0	2.0	3.0	2.5	
Min, Max	1, 4	0, 4	2, 4	1, 4	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-0.25 (0.145)	-0.72 (0.109)	-0.04 (1.061)	-0.24 (0.812)	
95% CI [2]	-0.54, 0.03	-0.93, -0.50	-2.40, 2.33	-2.05, 1.57	
Difference (95% CI) in CFB [2]		-0.46 (-0.78, -0.14)		-0.20 (-2.17, 1.76)	
p-value [3]		0.005		0.822	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-ecog-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.7a
Summary of PGIS by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	2.2 (0.90)	1.8 (0.88)	2.5 (0.58)	2.6 (0.97)	
Median	2.0	2.0	2.5	2.5	
Min, Max	1, 4	0, 4	2, 3	1, 4	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-0.19 (0.154)	-0.69 (0.117)	-0.54 (0.834)	-0.24 (0.639)	
95% CI [2]	-0.50, 0.11	-0.92, -0.46	-2.40, 1.32	-1.66, 1.18	
Difference (95% CI) in CFB [2]		-0.49 (-0.83, -0.16)		0.30 (-1.25, 1.84)	
Hedges'G (95% CI) in CFB		-0.41 (-0.74, -0.09)		0.14 (-1.12, 1.46)	
p-value [3]		0.004		0.678	
					0.200

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-ecog-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.8a
Summary of PGIS by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	3.0 (0.82)	3.2 (0.92)	2.7 (0.93)	2.6 (0.88)	
Median	3.0	3.5	3.0	3.0	
Min, Max	2, 4	2, 4	1, 4	1, 4	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-thpy-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.8a
Summary of PGIS by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	2.3 (0.96)	2.5 (0.97)	2.3 (0.75)	2.1 (0.87)	
Median	2.5	2.0	2.0	2.0	
Min, Max	1, 3	1, 4	1, 4	0, 4	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	-0.77 (0.592)	-0.90 (0.592)	-0.29 (0.137)	-0.49 (0.105)	
95% CI [2]	-2.09, 0.55	-2.22, 0.42	-0.56, -0.02	-0.70, -0.29	
Difference (95% CI) in CFB [2]		-0.13 (-1.81, 1.54)		-0.21 (-0.51, 0.09)	
p-value [3]		0.864		0.171	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-thpy-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.8a
Summary of PGIS by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	118	
Mean (StdDev)	2.3 (0.96)	2.2 (0.79)	2.4 (0.84)	1.9 (0.83)	
Median	2.5	2.0	2.0	2.0	
Min, Max	1, 3	1, 4	1, 4	0, 4	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	-0.76 (0.594)	-0.91 (0.594)	-0.17 (0.152)	-0.69 (0.115)	
95% CI [2]	-2.08, 0.57	-2.23, 0.42	-0.47, 0.13	-0.92, -0.47	
Difference (95% CI) in CFB [2]		-0.15 (-1.84, 1.53)		-0.52 (-0.85, -0.19)	
p-value [3]		0.846		0.002	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-thpy-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.8a
Summary of PGIS by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	119	
Mean (StdDev)	2.7 (0.58)	2.1 (0.93)	2.3 (0.89)	1.9 (0.80)	
Median	3.0	2.0	2.0	2.0	
Min, Max	2, 3	1, 4	1, 4	0, 4	
C4D1 CFB					
n	3	9	54	115	
LS Mean (StdErr) [2]	-0.94 (0.754)	-1.16 (0.565)	-0.24 (0.154)	-0.69 (0.115)	
95% CI [2]	-2.68, 0.80	-2.46, 0.15	-0.54, 0.06	-0.91, -0.46	
Difference (95% CI) in CFB [2]		-0.22 (-2.21, 1.77)		-0.45 (-0.78, -0.11)	
p-value [3]		0.806		0.009	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-thpy-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.8a
Summary of PGIS by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	117	
Mean (StdDev)	1.8 (0.96)	1.9 (0.64)	2.3 (0.91)	1.8 (0.81)	
Median	1.5	2.0	2.0	2.0	
Min, Max	1, 3	1, 3	0, 4	0, 4	
C5D1 CFB					
n	4	8	58	111	
LS Mean (StdErr) [2]	-1.04 (0.558)	-0.96 (0.558)	-0.24 (0.154)	-0.74 (0.118)	
95% CI [2]	-2.32, 0.25	-2.25, 0.32	-0.55, 0.06	-0.97, -0.50	
Difference (95% CI) in CFB [2]		0.08 (-1.57, 1.72)		-0.49 (-0.83, -0.16)	
p-value [3]		0.917		0.004	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-thpy-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.8a
Summary of PGIS by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	2.5 (0.58)	2.1 (1.17)	2.3 (0.86)	1.9 (0.86)	
Median	2.5	2.0	2.0	2.0	
Min, Max	2, 3	1, 4	1, 4	0, 4	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-0.53 (0.657)	-1.14 (0.657)	-0.23 (0.150)	-0.65 (0.112)	
95% CI [2]	-2.02, 0.96	-2.62, 0.35	-0.53, 0.07	-0.87, -0.43	
Difference (95% CI) in CFB [2]		-0.61 (-2.51, 1.29)		-0.42 (-0.75, -0.10)	
p-value [3]		0.486		0.012	

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-thpy-a.sas Date: 15:47/07AUG2023

Table 35.2.6.1.8a
Summary of PGIS by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	2.3 (0.96)	1.8 (0.71)	2.3 (0.89)	1.9 (0.92)	
Median	2.5	2.0	2.0	2.0	
Min, Max	1, 3	1, 3	1, 4	0, 4	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-0.62 (0.510)	-1.38 (0.510)	-0.20 (0.157)	-0.61 (0.118)	
95% CI [2]	-1.79, 0.56	-2.56, -0.21	-0.51, 0.11	-0.85, -0.38	
Difference (95% CI) in CFB [2]		-0.77 (-2.27, 0.74)		-0.42 (-0.75, -0.08)	
Hedges'G (95% CI) in CFB		-0.53 (-2.06, 0.72)		-0.34 (-0.67, -0.02)	
p-value [3]		0.272		0.016	
					0.788

Abbreviations: PGIS = Patient Global Impression of Symptom Severity, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-sum-g-itt-thpy-a.sas Date: 15:47/07AUG2023

Table 35.2.6.3.1a
Proportion of Patients with PGIS Change from Baseline <= -1 at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIS Change from Baseline <= -1 at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	24/ 71 (33.8) (23.0, 46.0)	72/141 (51.1) (42.5, 59.6)	2.17 (1.13, 4.12) 0.012	1.54 (1.07, 2.21) 0.020	0.18 (0.04, 0.32) 0.009	
Age Group (Years)						0.619
< 65	22/ 60 (36.7) (24.6, 50.1)	68/132 (51.5) (42.7, 60.3)	1.92 (0.96, 3.81) 0.048	1.42 (0.98, 2.05) 0.064	0.15 (0.01, 0.30) 0.041	
>= 65	2/ 11 (18.2) (2.3, 51.8)	4/ 9 (44.4) (13.7, 78.8)	2.22 (0.18, 34.12) 0.447	2.22 (0.18, 27.26) 0.532	0.18 (-0.28, 0.64) 0.448	
Sex						0.720
Male	5/ 17 (29.4) (10.3, 56.0)	17/ 41 (41.5) (26.3, 57.9)	1.85 (0.46, 8.02) 0.343	1.45 (0.65, 3.20) 0.362	0.13 (-0.12, 0.39) 0.314	
Female	19/ 54 (35.2) (22.7, 49.4)	55/100 (55.0) (44.7, 65.0)	2.29 (1.09, 4.85) 0.018	1.58 (1.05, 2.39) 0.030	0.20 (0.04, 0.36) 0.014	

Abbreviations: PGIS = Patients Global Impression of Symptom Severity, CI = Confidence Interval
PGIS: 0=Absent, 1=Minimal, 2=Moderate, 3=Severe, 4=Very Severe
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-resp-itt-a.sas Date: 12:01/10AUG2023

Table 35.2.6.3.1a
Proportion of Patients with PGIS Change from Baseline <= -1 at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIS Change from Baseline <= -1 at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Region						0.331
North America	8/ 33 (24.2) (11.1, 42.3)	29/ 60 (48.3) (35.2, 61.6)	3.37 (1.14, 9.94) 0.014	2.07 (1.09, 3.94) 0.026	0.26 (0.07, 0.45) 0.008	
Europe	16/ 38 (42.1) (26.3, 59.2)	43/ 81 (53.1) (41.7, 64.3)	1.56 (0.67, 3.67) 0.264	1.26 (0.82, 1.93) 0.283	0.11 (-0.08, 0.30) 0.255	
Country						NA
BEL	1/ 1 (100.0) (2.5, 100.0)	1/ 3 (33.3) (0.8, 90.6)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
CAN	1/ 5 (20.0) (0.5, 71.6)	4/ 8 (50.0) (15.7, 84.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
CHE	0/ 1 (0.0) (0.0, 97.5)	1/ 2 (50.0) (1.3, 98.7)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
DEU	8/ 15 (53.3) (26.6, 78.7)	5/ 19 (26.3) (9.1, 51.2)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	

Abbreviations: PGIS = Patients Global Impression of Symptom Severity, CI = Confidence Interval
PGIS: 0=Absent, 1=Minimal, 2=Moderate, 3=Severe, 4=Very Severe
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-resp-itt-a.sas Date: 12:01/10AUG2023

Table 35.2.6.3.1a
Proportion of Patients with PGIS Change from Baseline <= -1 at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIS Change from Baseline <= -1 at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
DNK	0/0	1/ 1 (100.0)	NA	NA	NA	
		(2.5, 100.0)	(NA, NA)	(NA, NA)	(NA, NA)	
			NA	NA	NA	
ESP	2/ 3 (66.7)	9/ 14 (64.3)	NA	NA	NA	
	(9.4, 99.2)	(35.1, 87.2)	(NA, NA)	(NA, NA)	(NA, NA)	
			NA	NA	NA	
FRA	3/ 6 (50.0)	8/ 11 (72.7)	NA	NA	NA	
	(11.8, 88.2)	(39.0, 94.0)	(NA, NA)	(NA, NA)	(NA, NA)	
			NA	NA	NA	
GBR	1/ 5 (20.0)	7/ 11 (63.6)	NA	NA	NA	
	(0.5, 71.6)	(30.8, 89.1)	(NA, NA)	(NA, NA)	(NA, NA)	
			NA	NA	NA	
ITA	0/0	2/ 4 (50.0)	NA	NA	NA	
		(6.8, 93.2)	(NA, NA)	(NA, NA)	(NA, NA)	
			NA	NA	NA	
NLD	0/ 3 (0.0)	5/ 9 (55.6)	NA	NA	NA	
	(0.0, 70.8)	(21.2, 86.3)	(NA, NA)	(NA, NA)	(NA, NA)	
			NA	NA	NA	
NOR	1/ 3 (33.3)	3/ 5 (60.0)	NA	NA	NA	
	(0.8, 90.6)	(14.7, 94.7)	(NA, NA)	(NA, NA)	(NA, NA)	
			NA	NA	NA	

Abbreviations: PGIS = Patients Global Impression of Symptom Severity, CI = Confidence Interval
PGIS: 0=Absent, 1=Minimal, 2=Moderate, 3=Severe, 4=Very Severe
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-resp-itt-a.sas Date: 12:01/10AUG2023

Table 35.2.6.3.1a
Proportion of Patients with PGIS Change from Baseline <= -1 at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIS Change from Baseline <= -1 at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
SWE	0/ 1 (0.0) (0.0, 97.5)	1/ 2 (50.0) (1.3, 98.7)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
USA	7/ 28 (25.0) (10.7, 44.9)	25/ 52 (48.1) (34.0, 62.4)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	
Baseline ISM Status						0.821
Moderate	8/ 26 (30.8) (14.3, 51.8)	25/ 52 (48.1) (34.0, 62.4)	2.60 (0.81, 8.41) 0.078	1.68 (0.90, 3.13) 0.103	0.20 (-0.01, 0.41) 0.059	
Severe	16/ 45 (35.6) (21.9, 51.2)	46/ 87 (52.9) (41.9, 63.7)	1.98 (0.89, 4.48) 0.071	1.47 (0.94, 2.29) 0.091	0.17 (-0.01, 0.34) 0.063	
Baseline Serum Tryptase (ng/mL)						0.359
< 20	4/ 15 (26.7) (7.8, 55.1)	8/ 28 (28.6) (13.2, 48.7)	1.39 (0.26, 8.17) 0.679	1.24 (0.45, 3.45) 0.678	0.06 (-0.21, 0.33) 0.660	
>= 20	20/ 56 (35.7) (23.4, 49.6)	64/113 (56.6) (47.0, 65.9)	2.37 (1.16, 4.84) 0.011	1.59 (1.08, 2.34) 0.019	0.21 (0.06, 0.37) 0.008	

Abbreviations: PGIS = Patients Global Impression of Symptom Severity, CI = Confidence Interval
PGIS: 0=Absent, 1=Minimal, 2=Moderate, 3=Severe, 4=Very Severe
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-resp-itt-a.sas Date: 12:01/10AUG2023

Table 35.2.6.3.1a
Proportion of Patients with PGIS Change from Baseline <= -1 at C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients with PGIS Change from Baseline <= -1 at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.343
0 or 1	22/ 67 (32.8) (21.8, 45.4)	68/131 (51.9) (43.0, 60.7)	2.37 (1.20, 4.62) 0.007	1.61 (1.11, 2.36) 0.013	0.20 (0.06, 0.34) 0.005	
2+	2/ 4 (50.0) (6.8, 93.2)	4/ 10 (40.0) (12.2, 73.8)	0.74 (0.04, 14.20) 0.822	0.85 (0.24, 3.04) >0.999	-0.07 (-0.67, 0.52) 0.807	
Prior TKI therapy						0.974
Yes	2/ 4 (50.0) (6.8, 93.2)	7/ 10 (70.0) (34.8, 93.3)	NE (0.27, NE) 0.156	2.44 (0.47, 12.71) 0.290	0.43 (0.08, 0.79) 0.016	
No	22/ 67 (32.8) (21.8, 45.4)	65/131 (49.6) (40.8, 58.5)	2.13 (1.09, 4.18) 0.018	1.54 (1.05, 2.27) 0.027	0.18 (0.04, 0.32) 0.013	

Abbreviations: PGIS = Patients Global Impression of Symptom Severity, CI = Confidence Interval
PGIS: 0=Absent, 1=Minimal, 2=Moderate, 3=Severe, 4=Very Severe
Note: Patient reached C7D1 or EOS prior to C7D1 with missing C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-pgis-resp-itt-a.sas Date: 12:01/10AUG2023

Table 35.1.4.4.1a
Proportion of Patients with BSC Decrease or Completely Discontinued at C7D1
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patients with BSC Decrease / Discontinued at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	9/ 71 (12.7) (6.0, 22.7)	34/141 (24.1) (17.3, 32.0)	2.23 (0.95, 5.61) 0.048	1.92 (0.98, 3.78) 0.059	0.12 (0.01, 0.22) 0.030	
Age Group (Years)						0.076
< 65	8/ 60 (13.3) (5.9, 24.6)	28/132 (21.2) (14.6, 29.2)	1.77 (0.71, 4.76) 0.195	1.60 (0.77, 3.32) 0.207	0.08 (-0.03, 0.19) 0.160	
>= 65	1/ 11 (9.1) (0.2, 41.3)	6/ 9 (66.7) (29.9, 92.5)	10.30 (0.74, 570.27) 0.032	4.10 (0.90, 18.63) 0.068	0.50 (0.08, 0.93) 0.021	
Sex						0.895
Male	2/ 17 (11.8) (1.5, 36.4)	10/ 41 (24.4) (12.4, 40.3)	2.60 (0.42, 27.50) 0.265	2.07 (0.53, 8.00) 0.294	0.13 (-0.07, 0.32) 0.201	
Female	7/ 54 (13.0) (5.4, 24.9)	24/100 (24.0) (16.0, 33.6)	2.06 (0.79, 6.14) 0.113	1.82 (0.84, 3.93) 0.127	0.11 (-0.02, 0.24) 0.088	

Abbreviations: BSC = Best Supportive Care.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-cm-bsc-c7d1-itt-a.sas Date: 17:57/13APR2023

Table 35.1.4.4.1a
Proportion of Patients with BSC Decrease or Completely Discontinued at C7D1
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patients with BSC Decrease / Discontinued at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Region						0.622
North America	3/ 33 (9.1) (1.9, 24.3)	13/ 60 (21.7) (12.1, 34.2)	2.95 (0.68, 16.43) 0.121	2.59 (0.71, 9.48) 0.150	0.13 (-0.01, 0.28) 0.075	
Europe	6/ 38 (15.8) (6.0, 31.3)	21/ 81 (25.9) (16.8, 36.9)	1.86 (0.64, 6.18) 0.223	1.64 (0.72, 3.74) 0.239	0.10 (-0.05, 0.25) 0.188	
Country						0.998
BEL	0/ 1 (0.0) (0.0, 97.5)	0/ 3 (0.0) (0.0, 70.8)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
CAN	1/ 5 (20.0) (0.5, 71.6)	3/ 8 (37.5) (8.5, 75.5)	0.67 (0.01, 58.83) 0.808	0.67 (0.02, 21.81) >0.999	-0.08 (-0.68, 0.52) 0.794	
CHE	0/ 1 (0.0) (0.0, 97.5)	1/ 2 (50.0) (1.3, 98.7)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DEU	1/ 15 (6.7) (0.2, 31.9)	3/ 19 (15.8) (3.4, 39.6)	2.14 (0.15, 133.68) 0.492	2.04 (0.24, 17.37) 0.514	0.08 (-0.14, 0.29) 0.484	
DNK	0/0	0/ 1 (0.0) (0.0, 97.5)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: BSC = Best Supportive Care.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-cm-bsc-c7d1-itt-a.sas Date: 17:57/13APR2023

Table 35.1.4.4.1a
Proportion of Patients with BSC Decrease or Completely Discontinued at C7D1
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patients with BSC Decrease / Discontinued at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
ESP	0/ 3 (0.0) (0.0, 70.8)	5/ 14 (35.7) (12.8, 64.9)	NE (0.31, NE) 0.183	NE (NE, NE) NE	0.44 (0.15, 0.73) 0.003	
FRA	1/ 6 (16.7) (0.4, 64.1)	1/ 11 (9.1) (0.2, 41.3)	0.00 (0.00, 6.33) 0.083	0.00 (NE, NE) NE	-0.23 (-0.57, 0.10) 0.173	
GBR	2/ 5 (40.0) (5.3, 85.3)	4/ 11 (36.4) (10.9, 69.2)	1.95 (0.11, 41.73) 0.632	1.38 (0.38, 4.97) 0.622	0.14 (-0.36, 0.64) 0.587	
ITA	0/0	1/ 4 (25.0) (0.6, 80.6)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
NLD	1/ 3 (33.3) (0.8, 90.6)	3/ 9 (33.3) (7.5, 70.1)	4.00 (0.07, 352.00) 0.456	2.00 (0.33, 11.97) 0.448	0.33 (-0.42, 1.00) 0.386	
NOR	1/ 3 (33.3) (0.8, 90.6)	2/ 5 (40.0) (5.3, 85.3)	1.33 (0.05, 98.03) 0.861	1.22 (0.15, 9.92) 0.851	0.07 (-0.64, 0.78) 0.844	

Abbreviations: BSC = Best Supportive Care.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-cm-bsc-c7d1-itt-a.sas Date: 17:57/13APR2023

Table 35.1.4.4.1a
Proportion of Patients with BSC Decrease or Completely Discontinued at C7D1
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patients with BSC Decrease / Discontinued at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
SWE	0/ 1 (0.0) (0.0, 97.5)	1/ 2 (50.0) (1.3, 98.7)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
USA	2/ 28 (7.1) (0.9, 23.5)	10/ 52 (19.2) (9.6, 32.5)	3.22 (0.58, 31.92) 0.147	2.68 (0.64, 11.20) 0.176	0.12 (-0.02, 0.27) 0.096	
Baseline ISM Status						0.238
Moderate	2/ 26 (7.7) (0.9, 25.1)	14/ 52 (26.9) (15.6, 41.0)	4.84 (0.92, 45.95) 0.041	3.69 (0.90, 15.16) 0.070	0.20 (0.04, 0.36) 0.012	
Severe	7/ 45 (15.6) (6.5, 29.5)	20/ 87 (23.0) (14.6, 33.2)	1.56 (0.56, 4.78) 0.361	1.43 (0.66, 3.11) 0.369	0.07 (-0.07, 0.21) 0.336	
Baseline Serum Tryptase (ng/mL)						0.970
< 20	1/ 15 (6.7) (0.2, 31.9)	4/ 28 (14.3) (4.0, 32.7)	2.39 (0.19, 121.38) 0.474	2.22 (0.23, 21.01) 0.487	0.08 (-0.10, 0.26) 0.410	
>= 20	8/ 56 (14.3) (6.4, 26.2)	30/113 (26.5) (18.7, 35.7)	2.21 (0.90, 6.01) 0.065	1.89 (0.93, 3.83) 0.079	0.13 (0.00, 0.25) 0.044	

Abbreviations: BSC = Best Supportive Care.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-cm-bsc-c7d1-itt-a.sas Date: 17:57/13APR2023

Table 35.1.4.4.1a
Proportion of Patients with BSC Decrease or Completely Discontinued at C7D1
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Patients with BSC Decrease / Discontinued at C7D1	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.978
0 or 1	9/ 67 (13.4) (6.3, 24.0)	29/131 (22.1) (15.4, 30.2)	1.84 (0.77, 4.72) 0.144	1.65 (0.83, 3.28) 0.156	0.09 (-0.02, 0.20) 0.116	
2+	0/ 4 (0.0) (0.0, 60.2)	5/ 10 (50.0) (18.7, 81.3)	NE (0.47, NE) 0.115	NE (NE, NE) NE	0.48 (0.16, 0.80) 0.003	
Prior TKI therapy						0.199
Yes	1/ 4 (25.0) (0.6, 80.6)	1/ 10 (10.0) (0.3, 44.5)	0.19 (0.00, 25.18) 0.347	0.19 (0.00, 9.35) >0.999	-0.25 (-0.79, 0.30) 0.374	
No	8/ 67 (11.9) (5.3, 22.2)	33/131 (25.2) (18.0, 33.5)	2.54 (1.04, 6.75) 0.028	2.12 (1.04, 4.30) 0.038	0.13 (0.03, 0.24) 0.014	

Abbreviations: BSC = Best Supportive Care.

[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).

[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.

Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-cm-bsc-c7d1-itt-a.sas Date: 17:57/13APR2023

Table 35.1.1.17a
Proportion of Patients with Anaphylaxis Based on Epinephrine Use Post Baseline
Safety Population, Part 2 (Part 2 Baseline)

Patients with Anaphylaxis Based on Epinephrine Use Post Baseline	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	3/ 71 (4.2) (0.9, 11.9)	2/141 (1.4) (0.2, 5.0)	0.33 (0.03, 2.98) 0.212	0.33 (0.05, 2.05) >0.999	-0.03 (-0.08, 0.02) 0.284	
Age Group (Years)						0.974
< 65	2/ 60 (3.3) (0.4, 11.5)	2/132 (1.5) (0.2, 5.4)	0.46 (0.03, 6.28) 0.413	0.46 (0.07, 3.13) >0.999	-0.02 (-0.07, 0.03) 0.479	
>= 65	1/ 11 (9.1) (0.2, 41.3)	0/ 9 (0.0) (0.0, 33.6)	0.00 (0.00, 44.33) 0.513	0.00 (NE, NE) NE	-0.07 (-0.25, 0.10) 0.418	
Sex						0.998
Male	0/ 17 (0.0) (0.0, 19.5)	0/ 41 (0.0) (0.0, 8.6)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
Female	3/ 54 (5.6) (1.2, 15.4)	2/100 (2.0) (0.2, 7.0)	0.36 (0.03, 3.25) 0.252	0.36 (0.06, 2.26) >0.999	-0.04 (-0.10, 0.03) 0.310	

Abbreviations: CI = Confidence Interval
Note: Safety population is used as the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR<1 or RR<1 or RD<0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-anaphlaxis-epinephrine-a.sas Date: 16:34/16SEP2025

Table 35.1.1.17a
Proportion of Patients with Anaphylaxis Based on Epinephrine Use Post Baseline
Safety Population, Part 2 (Part 2 Baseline)

Patients with Anaphylaxis Based on Epinephrine Use Post Baseline	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Region						0.977
North America	2/ 33 (6.1) (0.7, 20.2)	2/ 60 (3.3) (0.4, 11.5)	0.62 (0.04, 8.90) 0.610	0.62 (0.10, 3.99) >0.999	-0.02 (-0.12, 0.08) 0.643	
Europe	1/ 38 (2.6) (0.1, 13.8)	0/ 81 (0.0) (0.0, 4.5)	0.00 (0.00, 8.77) 0.141	0.00 (NE, NE) NE	-0.03 (-0.08, 0.02) 0.309	
Country						>0.999
BEL	0/ 1 (0.0) (0.0, 97.5)	0/ 3 (0.0) (0.0, 70.8)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
CAN	1/ 5 (20.0) (0.5, 71.6)	1/ 8 (12.5) (0.3, 52.7)	0.00 (0.00, 57.00) 0.564	0.00 (NE, NE) NE	-0.12 (-0.46, 0.22) 0.485	
CHE	0/ 1 (0.0) (0.0, 97.5)	0/ 2 (0.0) (0.0, 84.2)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DEU	0/ 15 (0.0) (0.0, 21.8)	0/ 19 (0.0) (0.0, 17.6)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DNK	0/0	0/ 1 (0.0) (0.0, 97.5)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: CI = Confidence Interval
Note: Safety population is used as the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR<1 or RR<1 or RD<0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-anaphlaxis-epinephrine-a.sas Date: 16:34/16SEP2025

Table 35.1.1.17a
Proportion of Patients with Anaphylaxis Based on Epinephrine Use Post Baseline
Safety Population, Part 2 (Part 2 Baseline)

Patients with Anaphylaxis Based on Epinephrine Use Post Baseline	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
ESP	1/ 3 (33.3) (0.8, 90.6)	0/ 14 (0.0) (0.0, 23.2)	0.00 (0.00, 6.33) 0.083	0.00 (NE, NE) NE	-0.32 (-0.85, 0.22) 0.243	
FRA	0/ 6 (0.0) (0.0, 45.9)	0/ 11 (0.0) (0.0, 28.5)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
GBR	0/ 5 (0.0) (0.0, 52.2)	0/ 11 (0.0) (0.0, 28.5)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
ITA	0/0	0/ 4 (0.0) (0.0, 60.2)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
NLD	0/ 3 (0.0) (0.0, 70.8)	0/ 9 (0.0) (0.0, 33.6)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
NOR	0/ 3 (0.0) (0.0, 70.8)	0/ 5 (0.0) (0.0, 52.2)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: CI = Confidence Interval
Note: Safety population is used as the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR<1 or RR<1 or RD<0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-anaphlaxis-epinephrine-a.sas Date: 16:34/16SEP2025

Table 35.1.1.17a
Proportion of Patients with Anaphylaxis Based on Epinephrine Use Post Baseline
Safety Population, Part 2 (Part 2 Baseline)

Patients with Anaphylaxis Based on Epinephrine Use Post Baseline	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
SWE	0/ 1 (0.0) (0.0, 97.5)	0/ 2 (0.0) (0.0, 84.2)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
USA	1/ 28 (3.6) (0.1, 18.3)	1/ 52 (1.9) (0.0, 10.3)	0.88 (0.01, 73.27) 0.908	0.88 (0.10, 7.98) >0.999	-0.00 (-0.09, 0.08) 0.919	
Baseline ISM Status						0.608
Moderate	2/ 26 (7.7) (0.9, 25.1)	1/ 52 (1.9) (0.0, 10.3)	0.19 (0.00, 4.52) 0.193	0.19 (0.01, 3.10) >0.999	-0.06 (-0.17, 0.05) 0.271	
Severe	1/ 45 (2.2) (0.1, 11.8)	1/ 87 (1.1) (0.0, 6.2)	0.60 (0.01, 45.77) 0.692	0.60 (0.05, 7.59) >0.999	-0.01 (-0.06, 0.04) 0.724	
Baseline Serum Tryptase (ng/mL)						0.955
< 20	0/ 15 (0.0) (0.0, 21.8)	2/ 28 (7.1) (0.9, 23.5)	NE (0.14, NE) 0.315	NE (NE, NE) NE	0.07 (-0.03, 0.17) 0.161	
>= 20	3/ 56 (5.4) (1.1, 14.9)	0/113 (0.0) (0.0, 3.2)	0.00 (0.00, 0.89) 0.016	0.00 (NE, NE) NE	-0.05 (-0.11, 0.01) 0.077	

Abbreviations: CI = Confidence Interval
Note: Safety population is used as the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR<1 or RR<1 or RD<0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-anaphlaxis-epinephrine-a.sas Date: 16:34/16SEP2025

Table 35.1.1.17a
Proportion of Patients with Anaphylaxis Based on Epinephrine Use Post Baseline
Safety Population, Part 2 (Part 2 Baseline)

Patients with Anaphylaxis Based on Epinephrine Use Post Baseline	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.997
0 or 1	3/ 67 (4.5) (0.9, 12.5)	2/131 (1.5) (0.2, 5.4)	0.34 (0.03, 3.02) 0.217	0.34 (0.06, 2.05) >0.999	-0.03 (-0.08, 0.03) 0.289	
2+	0/ 4 (0.0) (0.0, 60.2)	0/ 10 (0.0) (0.0, 30.8)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
Prior TKI therapy						0.996
Yes	0/ 4 (0.0) (0.0, 60.2)	0/ 10 (0.0) (0.0, 30.8)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
No	3/ 67 (4.5) (0.9, 12.5)	2/131 (1.5) (0.2, 5.4)	0.34 (0.03, 2.96) 0.209	0.34 (0.06, 2.02) >0.999	-0.03 (-0.08, 0.02) 0.282	

Abbreviations: CI = Confidence Interval
Note: Safety population is used as the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR<1 or RR<1 or RD<0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-anaphlaxis-epinephrine-a.sas Date: 16:34/16SEP2025

Table 35.2.11.4.1.1a
Summary of Mastocytosis in Skin by Age Group
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	29	67	8	7	
Mean (StdDev)	14.9 (26.66)	8.1 (16.99)	36.6 (38.44)	28.7 (41.58)	
Median	2.0	2.0	18.0	8.0	
Min, Max	0, 92	0, 91	0, 91	1, 97	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-age-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.1a
Summary of Mastocytosis in Skin by Age Group
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	22	45	5	6	
Mean (StdDev)	17.7 (31.67)	5.2 (11.61)	34.2 (38.38)	29.3 (41.65)	
Median	3.0	2.0	18.0	4.5	
Min, Max	0, 97	0, 61	1, 78	0, 86	
C4D1 CFB					
n	22	45	5	6	
LS Mean (StdErr) [2]	1.33 (0.769)	-1.50 (0.567)	-2.70 (4.090)	-6.70 (5.694)	
95% CI [2]	-0.21, 2.87	-2.63, -0.37	-12.37, 6.97	-20.16, 6.76	
Difference (95% CI) in CFB [2]		-2.83 (-4.53, -1.13)		-4.00 (-16.09, 8.09)	
p-value [3]		0.001		0.460	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-age-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.1a
Summary of Mastocytosis in Skin by Age Group
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	17	46	4	5	
Mean (StdDev)	17.2 (32.87)	6.0 (13.75)	30.5 (42.40)	35.0 (44.30)	
Median	1.0	1.0	14.0	5.0	
Min, Max	0, 98	0, 81	1, 93	1, 84	
C7D1 CFB					
n	17	46	4	5	
LS Mean (StdErr) [2]	1.17 (1.740)	-2.72 (1.120)	-0.14 (2.807)	-7.32 (4.248)	
95% CI [2]	-2.32, 4.65	-4.96, -0.48	-7.35, 7.08	-18.24, 3.60	
Difference (95% CI) in CFB [2]		-3.89 (-7.70, -0.07)		-7.18 (-17.22, 2.86)	
Hedges'G (95% CI) in CFB		-0.51 (-1.11, 0.04)		-0.79 (-2.77, 0.58)	
p-value [3]		0.046		0.125	
					0.840

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-age-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.1a
Summary of Mastocytosis in Skin by Age Group
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	29	67	8	7	
Mean (StdDev)	11.3 (22.84)	6.9 (15.48)	31.0 (33.56)	6.6 (6.24)	
Median	1.0	2.0	15.5	6.0	
Min, Max	0, 89	0, 91	1, 91	1, 17	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-age-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.1a
Summary of Mastocytosis in Skin by Age Group
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	22	45	5	6	
Mean (StdDev)	13.1 (25.18)	4.5 (10.48)	34.0 (39.30)	11.2 (17.95)	
Median	2.0	1.0	15.0	2.5	
Min, Max	0, 85	0, 56	0, 80	0, 46	
C4D1 CFB					
n	22	45	5	6	
LS Mean (StdErr) [2]	0.54 (0.781)	-1.54 (0.575)	-0.34 (8.045)	-6.14 (11.199)	
95% CI [2]	-1.02, 2.10	-2.69, -0.39	-19.36, 18.68	-32.62, 20.34	
Difference (95% CI) in CFB [2]		-2.08 (-3.81, -0.35)		-5.80 (-29.58, 17.98)	
p-value [3]		0.019		0.582	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-age-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.1a
Summary of Mastocytosis in Skin by Age Group
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	17	46	4	5	
Mean (StdDev)	12.2 (23.89)	4.9 (12.67)	30.3 (42.34)	6.2 (10.06)	
Median	2.0	1.5	13.5	2.0	
Min, Max	0, 79	0, 81	1, 93	0, 24	
C7D1 CFB					
n	17	46	4	5	
LS Mean (StdErr) [2]	-0.52 (2.162)	-2.35 (1.392)	-0.27 (2.971)	-6.64 (4.496)	
95% CI [2]	-4.85, 3.80	-5.14, 0.43	-7.91, 7.36	-18.19, 4.92	
Difference (95% CI) in CFB [2]		-1.83 (-6.57, 2.91)		-6.36 (-16.99, 4.26)	
Hedges'G (95% CI) in CFB		-0.19 (-0.77, 0.37)		-0.66 (-2.57, 0.73)	
p-value [3]		0.444		0.184	
					0.919

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-age-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.1a
Summary of Mastocytosis in Skin by Age Group
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	29	66	8	6	
Mean (StdDev)	9.3 (21.14)	5.7 (15.41)	32.3 (35.12)	30.7 (45.47)	
Median	1.0	1.0	18.0	2.0	
Min, Max	0, 92	0, 99	0, 86	1, 97	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-age-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.1a
Summary of Mastocytosis in Skin by Age Group
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	22	44	5	6	
Mean (StdDev)	10.0 (24.85)	2.1 (4.61)	30.0 (38.46)	28.0 (42.65)	
Median	1.0	1.0	18.0	1.0	
Min, Max	0, 97	0, 28	0, 93	0, 86	
C4D1 CFB					
n	22	44	5	6	
LS Mean (StdErr) [2]	1.00 (1.900)	-2.02 (1.409)	-1.04 (2.747)	-7.84 (3.824)	
95% CI [2]	-2.80, 4.80	-4.84, 0.79	-7.54, 5.46	-16.88, 1.20	
Difference (95% CI) in CFB [2]		-3.02 (-7.23, 1.18)		-6.80 (-14.92, 1.32)	
p-value [3]		0.156		0.088	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-age-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.1a
Summary of Mastocytosis in Skin by Age Group
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	17	46	4	5	
Mean (StdDev)	12.0 (27.88)	3.8 (11.68)	14.5 (13.20)	33.8 (45.37)	
Median	1.0	1.0	14.0	1.0	
Min, Max	0, 98	0, 73	0, 30	0, 84	
C7D1 CFB					
n	17	46	4	5	
LS Mean (StdErr) [2]	0.32 (2.575)	-2.85 (1.658)	-3.70 (2.688)	-6.48 (4.069)	
95% CI [2]	-4.84, 5.47	-6.17, 0.47	-10.62, 3.21	-16.94, 3.98	
Difference (95% CI) in CFB [2]		-3.16 (-8.81, 2.48)		-2.77 (-12.39, 6.84)	
Hedges'G (95% CI) in CFB		-0.28 (-0.86, 0.28)		-0.32 (-2.04, 1.16)	
p-value [3]		0.267		0.492	
					0.595

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-age-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.1a
Summary of Mastocytosis in Skin by Age Group
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	29	67	8	6	
Mean (StdDev)	13.9 (25.34)	8.0 (16.61)	34.3 (35.14)	22.0 (27.91)	
Median	2.0	3.0	16.0	9.0	
Min, Max	0, 88	0, 86	1, 82	2, 72	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-age-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.1a
Summary of Mastocytosis in Skin by Age Group
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	22	45	5	6	
Mean (StdDev)	15.7 (27.25)	5.4 (11.55)	32.6 (36.04)	20.0 (28.21)	
Median	3.0	2.0	18.0	4.5	
Min, Max	0, 75	0, 61	1, 78	0, 67	
C4D1 CFB					
n	22	45	5	6	
LS Mean (StdErr) [2]	0.06 (1.023)	-1.23 (0.753)	-0.68 (2.490)	-3.28 (3.467)	
95% CI [2]	-1.99, 2.10	-2.73, 0.28	-6.57, 5.21	-11.48, 4.92	
Difference (95% CI) in CFB [2]		-1.29 (-3.55, 0.97)		-2.60 (-9.96, 4.76)	
p-value [3]		0.260		0.431	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-age-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.1a
Summary of Mastocytosis in Skin by Age Group
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	17	46	4	5	
Mean (StdDev)	13.8 (27.73)	6.3 (14.58)	27.3 (33.42)	13.6 (15.31)	
Median	1.0	1.0	16.0	5.0	
Min, Max	0, 91	0, 87	1, 76	1, 34	
C7D1 CFB					
n	17	46	4	5	
LS Mean (StdErr) [2]	-1.12 (2.676)	-1.68 (1.723)	-2.70 (7.096)	-27.48 (10.738)	
95% CI [2]	-6.48, 4.23	-5.13, 1.77	-20.94, 15.54	-55.08, 0.13	
Difference (95% CI) in CFB [2]		-0.56 (-6.43, 5.31)		-24.77 (-50.15, 0.60)	
Hedges'G (95% CI) in CFB		-0.05 (-0.62, 0.52)		-1.08 (-3.24, 0.25)	
p-value [3]		0.849		0.054	
					0.106

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-age-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.1a
Summary of Mastocytosis in Skin by Age Group
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	29	67	8	6	
Mean (StdDev)	6.6 (13.95)	4.9 (11.68)	29.0 (33.01)	30.7 (42.10)	
Median	1.0	1.0	17.5	6.0	
Min, Max	0, 57	0, 84	0, 84	1, 93	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-age-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.1a
Summary of Mastocytosis in Skin by Age Group
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	22	45	5	6	
Mean (StdDev)	8.7 (20.32)	2.2 (4.35)	28.8 (36.53)	17.7 (25.59)	
Median	1.0	1.0	22.0	2.5	
Min, Max	0, 83	0, 27	1, 90	0, 58	
C4D1 CFB					
n	22	45	5	6	
LS Mean (StdErr) [2]	1.65 (1.185)	-1.49 (0.873)	-0.44 (8.356)	-21.24 (11.632)	
95% CI [2]	-0.71, 4.02	-3.24, 0.25	-20.20, 19.32	-48.74, 6.26	
Difference (95% CI) in CFB [2]		-3.15 (-5.77, -0.53)		-20.80 (-45.50, 3.90)	
p-value [3]		0.019		0.087	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-age-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.1a
Summary of Mastocytosis in Skin by Age Group
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	17	46	4	5	
Mean (StdDev)	9.4 (21.14)	3.0 (8.42)	16.0 (15.19)	21.8 (28.77)	
Median	1.0	1.0	14.0	4.0	
Min, Max	0, 65	0, 53	1, 35	1, 65	
C7D1 CFB					
n	17	46	4	5	
LS Mean (StdErr) [2]	1.09 (1.509)	-2.93 (0.972)	-3.14 (8.993)	-31.32 (13.609)	
95% CI [2]	-1.93, 4.11	-4.87, -0.98	-26.25, 19.98	-66.30, 3.67	
Difference (95% CI) in CFB [2]		-4.02 (-7.32, -0.71)		-28.18 (-60.34, 3.98)	
Hedges'G (95% CI) in CFB		-0.61 (-1.21, -0.05)		-0.97 (-3.05, 0.37)	
p-value [3]		0.018		0.074	
					0.031

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-age-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.2a
Summary of Mastocytosis in Skin by Sex
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	9	21	28	53	
Mean (StdDev)	23.7 (34.31)	12.8 (25.89)	18.3 (29.55)	8.9 (18.86)	
Median	3.0	4.0	2.0	2.0	
Min, Max	1, 92	0, 97	0, 91	0, 91	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-sex-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.2a
Summary of Mastocytosis in Skin by Sex
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	8	13	19	38	
Mean (StdDev)	23.8 (38.94)	15.0 (30.30)	19.5 (31.04)	5.7 (12.55)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 97	0, 86	0, 85	0, 61	
C4D1 CFB					
n	8	13	19	38	
LS Mean (StdErr) [2]	0.99 (1.724)	-2.44 (1.518)	0.10 (1.067)	-1.57 (0.816)	
95% CI [2]	-2.65, 4.63	-5.64, 0.76	-2.04, 2.24	-3.20, 0.07	
Difference (95% CI) in CFB [2]		-3.43 (-7.68, 0.82)		-1.66 (-4.02, 0.69)	
p-value [3]		0.107		0.162	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-sex-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.2a
Summary of Mastocytosis in Skin by Sex
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	6	13	15	38	
Mean (StdDev)	31.5 (44.61)	16.5 (29.91)	15.0 (29.44)	6.3 (15.05)	
Median	5.0	7.0	1.0	1.0	
Min, Max	1, 98	0, 84	0, 93	0, 81	
C7D1 CFB					
n	6	13	15	38	
LS Mean (StdErr) [2]	1.81 (2.338)	-3.26 (1.768)	0.57 (1.890)	-2.70 (1.302)	
95% CI [2]	-3.17, 6.80	-7.03, 0.51	-3.23, 4.36	-5.32, -0.09	
Difference (95% CI) in CFB [2]		-5.07 (-10.36, 0.21)		-3.27 (-7.53, 0.99)	
Hedges'G (95% CI) in CFB		-0.78 (-1.97, 0.19)		-0.41 (-1.05, 0.19)	
p-value [3]		0.059		0.130	
					0.587

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-sex-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.2a
Summary of Mastocytosis in Skin by Sex
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	9	21	28	53	
Mean (StdDev)	16.6 (29.73)	5.4 (5.01)	15.3 (25.71)	7.4 (17.26)	
Median	3.0	4.0	2.0	1.0	
Min, Max	0, 89	0, 17	0, 91	0, 91	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-sex-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.2a
Summary of Mastocytosis in Skin by Sex
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	8	13	19	38	
Mean (StdDev)	16.3 (28.49)	6.5 (12.61)	17.3 (29.41)	4.8 (11.33)	
Median	2.5	2.0	2.0	1.0	
Min, Max	1, 79	0, 46	0, 85	0, 56	
C4D1 CFB					
n	8	13	19	38	
LS Mean (StdErr) [2]	-1.37 (3.009)	0.15 (2.649)	1.01 (1.464)	-1.78 (1.120)	
95% CI [2]	-7.72, 4.98	-5.44, 5.74	-1.93, 3.94	-4.02, 0.47	
Difference (95% CI) in CFB [2]		1.52 (-5.89, 8.93)		-2.79 (-6.01, 0.44)	
p-value [3]		0.671		0.089	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-sex-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.2a
Summary of Mastocytosis in Skin by Sex
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	6	13	15	38	
Mean (StdDev)	18.3 (25.84)	4.8 (6.30)	14.6 (29.48)	5.1 (13.92)	
Median	3.5	3.0	2.0	1.0	
Min, Max	0, 59	0, 24	0, 93	0, 81	
C7D1 CFB					
n	6	13	15	38	
LS Mean (StdErr) [2]	-2.73 (3.930)	-1.71 (2.973)	0.71 (2.202)	-2.49 (1.517)	
95% CI [2]	-11.10, 5.65	-8.05, 4.63	-3.72, 5.13	-5.54, 0.55	
Difference (95% CI) in CFB [2]		1.02 (-7.87, 9.91)		-3.20 (-8.17, 1.76)	
Hedges'G (95% CI) in CFB		0.09 (-0.94, 1.15)		-0.35 (-0.98, 0.26)	
p-value [3]		0.811		0.201	
					0.383

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-sex-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.2a
Summary of Mastocytosis in Skin by Sex
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	9	20	28	52	
Mean (StdDev)	22.2 (34.08)	11.9 (26.75)	11.7 (23.10)	6.2 (17.23)	
Median	2.0	2.0	1.0	1.0	
Min, Max	1, 92	0, 97	0, 86	0, 99	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-sex-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.2a
Summary of Mastocytosis in Skin by Sex
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	8	13	19	37	
Mean (StdDev)	22.0 (38.90)	13.8 (30.74)	10.2 (22.53)	2.2 (5.00)	
Median	1.5	1.0	1.0	1.0	
Min, Max	0, 97	0, 86	0, 93	0, 28	
C4D1 CFB					
n	8	13	19	37	
LS Mean (StdErr) [2]	0.58 (1.716)	-2.38 (1.511)	0.60 (2.216)	-2.09 (1.710)	
95% CI [2]	-3.04, 4.20	-5.57, 0.80	-3.84, 5.05	-5.52, 1.34	
Difference (95% CI) in CFB [2]		-2.96 (-7.19, 1.27)		-2.69 (-7.59, 2.21)	
p-value [3]		0.158		0.275	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-sex-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.2a
Summary of Mastocytosis in Skin by Sex
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	6	13	15	38	
Mean (StdDev)	29.0 (43.52)	15.4 (30.35)	5.9 (9.33)	3.8 (12.81)	
Median	2.0	2.0	1.0	1.0	
Min, Max	1, 98	0, 84	0, 30	0, 73	
C7D1 CFB					
n	6	13	15	38	
LS Mean (StdErr) [2]	1.10 (1.901)	-2.66 (1.438)	-1.29 (2.947)	-2.92 (2.031)	
95% CI [2]	-2.95, 5.15	-5.72, 0.41	-7.21, 4.63	-7.00, 1.17	
Difference (95% CI) in CFB [2]		-3.76 (-8.06, 0.54)		-1.63 (-8.27, 5.02)	
Hedges'G (95% CI) in CFB		-0.71 (-1.89, 0.26)		-0.13 (-0.75, 0.48)	
p-value [3]		0.082		0.625	
					0.661

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-sex-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.2a
Summary of Mastocytosis in Skin by Sex
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	9	20	28	53	
Mean (StdDev)	21.4 (33.17)	10.3 (16.84)	17.3 (27.42)	8.7 (18.49)	
Median	3.0	5.5	2.0	2.0	
Min, Max	0, 88	0, 72	0, 82	0, 86	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-sex-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.2a
Summary of Mastocytosis in Skin by Sex
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	8	13	19	38	
Mean (StdDev)	20.0 (31.04)	11.2 (20.13)	18.4 (29.05)	5.8 (12.55)	
Median	3.0	4.0	2.0	2.0	
Min, Max	1, 75	0, 67	0, 78	0, 61	
C4D1 CFB					
n	8	13	19	38	
LS Mean (StdErr) [2]	-1.66 (2.406)	-1.25 (2.118)	0.48 (0.910)	-1.29 (0.696)	
95% CI [2]	-6.73, 3.42	-5.72, 3.22	-1.34, 2.30	-2.68, 0.11	
Difference (95% CI) in CFB [2]		0.41 (-5.52, 6.33)		-1.77 (-3.77, 0.24)	
p-value [3]		0.887		0.083	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-sex-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.2a
Summary of Mastocytosis in Skin by Sex
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	6	13	15	38	
Mean (StdDev)	19.8 (30.74)	9.0 (10.53)	14.9 (28.55)	6.3 (15.89)	
Median	5.0	7.0	1.0	1.0	
Min, Max	1, 79	0, 34	0, 91	0, 87	
C7D1 CFB					
n	6	13	15	38	
LS Mean (StdErr) [2]	-6.70 (8.721)	-3.09 (6.596)	1.93 (1.965)	-2.39 (1.354)	
95% CI [2]	-25.29, 11.89	-17.15, 10.97	-2.01, 5.88	-5.11, 0.34	
Difference (95% CI) in CFB [2]		3.61 (-16.12, 23.33)		-4.32 (-8.75, 0.11)	
Hedges'G (95% CI) in CFB		0.15 (-0.87, 1.21)		-0.52 (-1.17, 0.08)	
p-value [3]		0.702		0.056	
					0.221

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-sex-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.2a
Summary of Mastocytosis in Skin by Sex
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	9	20	28	53	
Mean (StdDev)	14.1 (22.88)	11.0 (25.64)	10.6 (21.04)	5.5 (12.87)	
Median	1.0	2.0	1.0	2.0	
Min, Max	0, 57	0, 93	0, 84	0, 84	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-sex-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.2a
Summary of Mastocytosis in Skin by Sex
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	8	13	19	38	
Mean (StdDev)	17.4 (32.03)	8.5 (18.74)	10.3 (21.34)	2.6 (4.69)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 83	0, 58	0, 90	0, 27	
C4D1 CFB					
n	8	13	19	38	
LS Mean (StdErr) [2]	2.71 (5.047)	-6.37 (4.443)	1.19 (1.075)	-1.44 (0.823)	
95% CI [2]	-7.93, 13.36	-15.74, 3.01	-0.97, 3.35	-3.09, 0.21	
Difference (95% CI) in CFB [2]		-9.08 (-21.51, 3.35)		-2.63 (-5.00, -0.26)	
p-value [3]		0.142		0.030	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-sex-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.2a
Summary of Mastocytosis in Skin by Sex
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	6	13	15	38	
Mean (StdDev)	21.8 (33.05)	9.6 (19.64)	6.2 (10.25)	3.2 (9.10)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 65	0, 65	0, 35	0, 53	
C7D1 CFB					
n	6	13	15	38	
LS Mean (StdErr) [2]	3.38 (6.248)	-6.20 (4.725)	0.25 (1.621)	-2.92 (1.117)	
95% CI [2]	-9.93, 16.70	-16.27, 3.87	-3.00, 3.51	-5.16, -0.67	
Difference (95% CI) in CFB [2]		-9.58 (-23.72, 4.55)		-3.17 (-6.83, 0.48)	
Hedges'G (95% CI) in CFB		-0.55 (-1.69, 0.43)		-0.46 (-1.10, 0.13)	
p-value [3]		0.169		0.087	
					0.153

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-sex-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.3a
Summary of Mastocytosis in Skin by Region
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	13	25	24	49	
Mean (StdDev)	19.8 (28.34)	10.0 (23.17)	19.5 (32.00)	10.1 (20.02)	
Median	7.0	2.0	2.0	2.0	
Min, Max	0, 91	0, 91	0, 92	0, 97	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-reg-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.3a
Summary of Mastocytosis in Skin by Region
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	6	14	21	37	
Mean (StdDev)	26.3 (36.21)	6.1 (15.89)	19.2 (32.60)	8.8 (19.95)	
Median	5.0	1.5	3.0	2.0	
Min, Max	1, 73	0, 61	0, 97	0, 86	
C4D1 CFB					
n	6	14	21	37	
LS Mean (StdErr) [2]	-1.55 (3.087)	-1.56 (2.692)	0.87 (0.736)	-1.72 (0.572)	
95% CI [2]	-8.09, 4.99	-7.27, 4.14	-0.60, 2.35	-2.86, -0.57	
Difference (95% CI) in CFB [2]		-0.01 (-7.72, 7.69)		-2.59 (-4.23, -0.94)	
p-value [3]		0.997		0.003	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-reg-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.3a
Summary of Mastocytosis in Skin by Region
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	5	13	16	38	
Mean (StdDev)	21.8 (39.96)	10.5 (22.84)	19.1 (33.51)	8.3 (19.34)	
Median	7.0	2.0	1.5	1.5	
Min, Max	0, 93	0, 81	0, 98	0, 84	
C7D1 CFB					
n	5	13	16	38	
LS Mean (StdErr) [2]	1.35 (5.875)	-3.93 (4.260)	0.80 (0.844)	-2.30 (0.587)	
95% CI [2]	-11.25, 13.95	-13.06, 5.21	-0.90, 2.49	-3.48, -1.12	
Difference (95% CI) in CFB [2]		-5.28 (-19.24, 8.69)		-3.10 (-4.99, -1.20)	
Hedges'G (95% CI) in CFB		-0.34 (-1.51, 0.73)		-0.86 (-1.52, -0.28)	
p-value [3]		0.431		0.002	
					0.460

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-reg-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.3a
Summary of Mastocytosis in Skin by Region
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	13	25	24	49	
Mean (StdDev)	15.4 (25.14)	9.5 (22.46)	15.7 (27.45)	5.4 (8.73)	
Median	7.0	3.0	1.0	2.0	
Min, Max	0, 91	0, 91	0, 89	0, 49	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-reg-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.3a
Summary of Mastocytosis in Skin by Region
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	6	14	21	37	
Mean (StdDev)	21.2 (30.41)	5.4 (14.64)	15.8 (28.73)	5.2 (10.40)	
Median	4.5	1.0	2.0	2.0	
Min, Max	0, 73	0, 56	0, 85	0, 46	
C4D1 CFB					
n	6	14	21	37	
LS Mean (StdErr) [2]	-2.01 (3.055)	-2.42 (2.664)	0.77 (1.493)	-0.85 (1.161)	
95% CI [2]	-8.48, 4.47	-8.06, 3.23	-2.22, 3.77	-3.18, 1.48	
Difference (95% CI) in CFB [2]		-0.41 (-8.03, 7.21)		-1.62 (-4.97, 1.72)	
p-value [3]		0.911		0.335	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-reg-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.3a
Summary of Mastocytosis in Skin by Region
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	5	13	16	38	
Mean (StdDev)	22.0 (39.89)	9.2 (22.30)	13.7 (24.41)	3.6 (6.09)	
Median	6.0	1.0	2.0	2.0	
Min, Max	0, 93	0, 81	0, 79	0, 27	
C7D1 CFB					
n	5	13	16	38	
LS Mean (StdErr) [2]	1.54 (6.484)	-4.60 (4.702)	-0.98 (1.510)	-1.50 (1.050)	
95% CI [2]	-12.36, 15.45	-14.68, 5.48	-4.02, 2.05	-3.61, 0.61	
Difference (95% CI) in CFB [2]		-6.14 (-21.55, 9.27)		-0.51 (-3.90, 2.88)	
Hedges'G (95% CI) in CFB		-0.36 (-1.53, 0.71)		-0.08 (-0.68, 0.52)	
p-value [3]		0.407		0.762	
					0.216

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-reg-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.3a
Summary of Mastocytosis in Skin by Region
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	13	23	24	49	
Mean (StdDev)	9.5 (14.16)	9.5 (24.71)	16.8 (30.64)	6.9 (18.07)	
Median	2.0	2.0	1.5	1.0	
Min, Max	0, 42	0, 99	0, 92	0, 97	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-reg-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.3a
Summary of Mastocytosis in Skin by Region
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	6	13	21	37	
Mean (StdDev)	7.2 (15.13)	1.7 (2.84)	15.6 (30.85)	6.5 (19.16)	
Median	1.5	1.0	1.0	1.0	
Min, Max	0, 38	0, 11	0, 97	0, 86	
C4D1 CFB					
n	6	13	21	37	
LS Mean (StdErr) [2]	1.22 (6.965)	-3.65 (6.158)	0.35 (0.769)	-1.64 (0.598)	
95% CI [2]	-13.62, 16.07	-16.78, 9.47	-1.19, 1.89	-2.84, -0.45	
Difference (95% CI) in CFB [2]		-4.87 (-22.26, 12.52)		-1.99 (-3.71, -0.27)	
p-value [3]		0.559		0.024	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-reg-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.3a
Summary of Mastocytosis in Skin by Region
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	5	13	16	38	
Mean (StdDev)	8.0 (12.73)	6.5 (19.98)	13.9 (28.52)	6.9 (19.19)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 30	0, 73	0, 98	0, 84	
C7D1 CFB					
n	5	13	16	38	
LS Mean (StdErr) [2]	-2.02 (9.112)	-7.14 (6.607)	-0.27 (0.859)	-1.39 (0.597)	
95% CI [2]	-21.56, 17.52	-21.31, 7.03	-1.99, 1.46	-2.59, -0.19	
Difference (95% CI) in CFB [2]		-5.12 (-26.78, 16.53)		-1.12 (-3.05, 0.81)	
Hedges'G (95% CI) in CFB		-0.21 (-1.36, 0.87)		-0.31 (-0.92, 0.28)	
p-value [3]		0.620		0.248	
					0.409

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-reg-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.3a
Summary of Mastocytosis in Skin by Region
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	13	24	24	49	
Mean (StdDev)	17.0 (24.21)	10.3 (22.80)	19.0 (31.04)	8.5 (15.26)	
Median	7.0	2.5	2.0	3.0	
Min, Max	0, 73	0, 86	0, 88	0, 72	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-reg-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.3a
Summary of Mastocytosis in Skin by Region
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	6	14	21	37	
Mean (StdDev)	24.5 (34.30)	6.4 (15.84)	17.2 (28.13)	7.4 (14.62)	
Median	5.0	2.0	3.0	2.0	
Min, Max	0, 73	0, 61	0, 78	0, 67	
C4D1 CFB					
n	6	14	21	37	
LS Mean (StdErr) [2]	-0.47 (2.606)	-3.13 (2.272)	-0.12 (0.930)	-0.83 (0.723)	
95% CI [2]	-5.99, 5.06	-7.94, 1.69	-1.98, 1.74	-2.28, 0.62	
Difference (95% CI) in CFB [2]		-2.66 (-9.16, 3.84)		-0.71 (-2.79, 1.37)	
p-value [3]		0.398		0.495	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-reg-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.3a
Summary of Mastocytosis in Skin by Region
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	5	13	16	38	
Mean (StdDev)	19.2 (32.12)	11.0 (24.39)	15.4 (28.36)	5.7 (9.48)	
Median	7.0	2.0	1.5	1.5	
Min, Max	0, 76	0, 87	0, 91	0, 40	
C7D1 CFB					
n	5	13	16	38	
LS Mean (StdErr) [2]	2.46 (5.862)	-2.55 (4.251)	-1.64 (2.918)	-2.45 (2.029)	
95% CI [2]	-10.11, 15.04	-11.66, 6.57	-7.51, 4.22	-6.53, 1.63	
Difference (95% CI) in CFB [2]		-5.01 (-18.94, 8.92)		-0.81 (-7.36, 5.74)	
Hedges'G (95% CI) in CFB		-0.32 (-1.49, 0.75)		-0.06 (-0.67, 0.53)	
p-value [3]		0.453		0.806	
					0.477

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-reg-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.3a
Summary of Mastocytosis in Skin by Region
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	13	24	24	49	
Mean (StdDev)	7.2 (8.57)	6.5 (17.62)	13.7 (25.52)	7.3 (17.31)	
Median	2.0	2.0	1.0	2.0	
Min, Max	0, 28	0, 84	0, 84	0, 93	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-reg-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.3a
Summary of Mastocytosis in Skin by Region
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	6	14	21	37	
Mean (StdDev)	6.7 (11.71)	1.2 (1.19)	14.0 (27.13)	5.1 (12.01)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 30	0, 4	0, 90	0, 58	
C4D1 CFB					
n	6	14	21	37	
LS Mean (StdErr) [2]	1.19 (2.971)	-2.30 (2.591)	1.92 (1.918)	-2.81 (1.492)	
95% CI [2]	-5.11, 7.49	-7.79, 3.20	-1.93, 5.77	-5.80, 0.18	
Difference (95% CI) in CFB [2]		-3.48 (-10.90, 3.93)		-4.73 (-9.03, -0.44)	
p-value [3]		0.334		0.031	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-reg-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.3a
Summary of Mastocytosis in Skin by Region
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	5	13	16	38	
Mean (StdDev)	8.6 (15.04)	4.9 (14.48)	11.3 (21.68)	4.8 (12.29)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 35	0, 53	0, 65	0, 65	
C7D1 CFB					
n	5	13	16	38	
LS Mean (StdErr) [2]	0.27 (4.666)	-5.61 (3.384)	1.03 (2.112)	-3.34 (1.469)	
95% CI [2]	-9.74, 10.28	-12.87, 1.65	-3.21, 5.27	-6.29, -0.39	
Difference (95% CI) in CFB [2]		-5.88 (-16.97, 5.21)		-4.37 (-9.11, 0.37)	
Hedges'G (95% CI) in CFB		-0.48 (-1.68, 0.58)		-0.48 (-1.11, 0.10)	
p-value [3]		0.275		0.070	
					0.610

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-reg-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.4a
Summary of Mastocytosis in Skin by Country
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-cou-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.4a
Summary of Mastocytosis in Skin by Country
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-cou-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.4a
Summary of Mastocytosis in Skin by Country
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-cou-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.4a
Summary of Mastocytosis in Skin by Country
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-cou-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.4a
Summary of Mastocytosis in Skin by Country
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-cou-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.4a
Summary of Mastocytosis in Skin by Country
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-cou-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.4a
Summary of Mastocytosis in Skin by Country
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-cou-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.4a
Summary of Mastocytosis in Skin by Country
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-cou-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.4a
Summary of Mastocytosis in Skin by Country
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-cou-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.4a
Summary of Mastocytosis in Skin by Country
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-cou-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.4a
Summary of Mastocytosis in Skin by Country
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-cou-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.4a
Summary of Mastocytosis in Skin by Country
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-cou-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.4a
Summary of Mastocytosis in Skin by Country
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-cou-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.4a
Summary of Mastocytosis in Skin by Country
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-cou-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.4a
Summary of Mastocytosis in Skin by Country
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-cou-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.4a
Summary of Mastocytosis in Skin by Country
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-cou-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.4a
Summary of Mastocytosis in Skin by Country
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-cou-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.4a
Summary of Mastocytosis in Skin by Country
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-cou-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.4a
Summary of Mastocytosis in Skin by Country
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-cou-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.4a
Summary of Mastocytosis in Skin by Country
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-cou-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.4a
Summary of Mastocytosis in Skin by Country
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-cou-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.4a
Summary of Mastocytosis in Skin by Country
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-cou-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.4a
Summary of Mastocytosis in Skin by Country
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-cou-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.4a
Summary of Mastocytosis in Skin by Country
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-cou-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.4a
Summary of Mastocytosis in Skin by Country
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-cou-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	13	30	24	44	
Mean (StdDev)	19.6 (31.01)	9.0 (20.22)	19.6 (30.68)	10.8 (21.68)	
Median	2.0	2.0	3.0	2.5	
Min, Max	0, 91	0, 97	0, 92	0, 91	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ism-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	8	20	19	31	
Mean (StdDev)	13.3 (24.96)	6.9 (17.68)	23.9 (35.79)	8.8 (19.75)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 73	0, 80	1, 97	0, 86	
C4D1 CFB					
n	8	20	19	31	
LS Mean (StdErr) [2]	-1.78 (1.889)	-1.47 (1.270)	1.70 (0.908)	-1.78 (0.804)	
95% CI [2]	-5.67, 2.12	-4.09, 1.15	-0.12, 3.53	-3.40, -0.16	
Difference (95% CI) in CFB [2]		0.31 (-3.79, 4.40)		-3.48 (-5.68, -1.29)	
p-value [3]		0.879		0.003	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ism-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	7	17	14	34	
Mean (StdDev)	18.0 (33.87)	8.4 (20.00)	20.6 (35.45)	9.1 (20.40)	
Median	1.0	2.0	2.5	1.0	
Min, Max	0, 93	0, 84	0, 98	0, 83	
C7D1 CFB					
n	7	17	14	34	
LS Mean (StdErr) [2]	0.75 (1.414)	-2.32 (0.893)	1.08 (2.093)	-3.33 (1.504)	
95% CI [2]	-2.19, 3.69	-4.18, -0.47	-3.14, 5.29	-6.36, -0.30	
Difference (95% CI) in CFB [2]		-3.07 (-6.30, 0.16)		-4.41 (-9.26, 0.43)	
Hedges'G (95% CI) in CFB		-0.80 (-1.85, 0.08)		-0.51 (-1.18, 0.11)	
p-value [3]		0.061		0.073	
					0.696

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ism-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	13	30	24	44	
Mean (StdDev)	17.3 (28.75)	4.4 (6.31)	14.6 (25.49)	8.5 (18.42)	
Median	1.0	2.0	3.0	1.5	
Min, Max	0, 91	0, 26	0, 89	0, 91	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ism-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	8	20	19	31	
Mean (StdDev)	12.1 (25.12)	3.0 (4.80)	19.1 (30.35)	6.7 (14.23)	
Median	1.0	1.0	3.0	2.0	
Min, Max	0, 73	0, 16	0, 85	0, 56	
C4D1 CFB					
n	8	20	19	31	
LS Mean (StdErr) [2]	-1.90 (1.448)	-0.82 (0.973)	1.58 (1.750)	-1.47 (1.549)	
95% CI [2]	-4.88, 1.08	-2.82, 1.19	-1.94, 5.10	-4.59, 1.64	
Difference (95% CI) in CFB [2]		1.08 (-2.06, 4.22)		-3.05 (-7.28, 1.18)	
p-value [3]		0.485		0.153	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ism-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	7	17	14	34	
Mean (StdDev)	16.9 (34.12)	2.8 (3.54)	15.1 (25.66)	6.1 (14.89)	
Median	1.0	2.0	2.5	1.0	
Min, Max	0, 93	0, 14	0, 79	0, 81	
C7D1 CFB					
n	7	17	14	34	
LS Mean (StdErr) [2]	1.16 (1.118)	-1.87 (0.705)	-1.38 (2.671)	-2.94 (1.919)	
95% CI [2]	-1.16, 3.49	-3.34, -0.40	-6.76, 3.99	-6.81, 0.92	
Difference (95% CI) in CFB [2]		-3.03 (-5.58, -0.48)		-1.56 (-7.74, 4.63)	
Hedges'G (95% CI) in CFB		-1.00 (-2.09, -0.12)		-0.14 (-0.79, 0.49)	
p-value [3]		0.022		0.615	
					0.739

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ism-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	13	28	24	44	
Mean (StdDev)	14.6 (24.25)	6.3 (18.22)	14.1 (27.50)	8.7 (21.64)	
Median	2.0	1.0	1.5	1.5	
Min, Max	0, 84	0, 97	0, 92	0, 99	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ism-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	8	19	19	31	
Mean (StdDev)	8.1 (13.52)	5.8 (18.10)	16.1 (32.39)	4.9 (15.95)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 38	0, 80	0, 97	0, 86	
C4D1 CFB					
n	8	19	19	31	
LS Mean (StdErr) [2]	-0.50 (1.446)	-1.50 (0.980)	0.89 (2.246)	-2.74 (1.989)	
95% CI [2]	-3.48, 2.48	-3.52, 0.52	-3.63, 5.41	-6.74, 1.26	
Difference (95% CI) in CFB [2]		-1.00 (-4.16, 2.16)		-3.63 (-9.06, 1.80)	
p-value [3]		0.520		0.185	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ism-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	7	17	14	34	
Mean (StdDev)	8.3 (11.95)	6.9 (20.03)	14.6 (30.31)	6.7 (19.07)	
Median	1.0	1.0	1.5	1.0	
Min, Max	0, 30	0, 84	0, 98	0, 83	
C7D1 CFB					
n	7	17	14	34	
LS Mean (StdErr) [2]	-1.18 (1.632)	-1.83 (1.030)	-0.34 (3.141)	-3.80 (2.257)	
95% CI [2]	-4.57, 2.22	-3.97, 0.31	-6.67, 5.99	-8.34, 0.75	
Difference (95% CI) in CFB [2]		-0.66 (-4.38, 3.07)		-3.46 (-10.73, 3.81)	
Hedges'G (95% CI) in CFB		-0.15 (-1.10, 0.77)		-0.27 (-0.92, 0.36)	
p-value [3]		0.718		0.343	
					0.579

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ism-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	13	29	24	44	
Mean (StdDev)	17.6 (27.78)	8.4 (16.85)	18.7 (29.46)	9.6 (18.81)	
Median	2.0	3.0	3.0	3.0	
Min, Max	0, 82	0, 72	0, 88	0, 86	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ism-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	8	20	19	31	
Mean (StdDev)	12.4 (21.74)	6.2 (14.84)	21.6 (31.77)	7.8 (15.00)	
Median	2.5	2.5	3.0	2.0	
Min, Max	0, 64	0, 67	0, 78	0, 61	
C4D1 CFB					
n	8	20	19	31	
LS Mean (StdErr) [2]	-0.68 (0.981)	-1.40 (0.659)	0.06 (1.228)	-1.22 (1.087)	
95% CI [2]	-2.70, 1.34	-2.76, -0.04	-2.41, 2.53	-3.41, 0.97	
Difference (95% CI) in CFB [2]		-0.71 (-2.84, 1.41)		-1.28 (-4.25, 1.68)	
p-value [3]		0.496		0.388	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ism-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	7	17	14	34	
Mean (StdDev)	15.6 (27.63)	5.1 (7.07)	16.7 (29.94)	8.0 (17.27)	
Median	1.0	2.0	2.5	1.0	
Min, Max	0, 76	0, 26	0, 91	0, 87	
C7D1 CFB					
n	7	17	14	34	
LS Mean (StdErr) [2]	1.95 (3.963)	-3.43 (2.501)	-1.81 (3.257)	-2.22 (2.340)	
95% CI [2]	-6.29, 10.19	-8.63, 1.77	-8.37, 4.75	-6.93, 2.50	
Difference (95% CI) in CFB [2]		-5.38 (-14.42, 3.66)		-0.40 (-7.94, 7.14)	
Hedges'G (95% CI) in CFB		-0.50 (-1.50, 0.39)		-0.03 (-0.67, 0.61)	
p-value [3]		0.230		0.915	
					0.419

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ism-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	13	29	24	44	
Mean (StdDev)	12.7 (21.28)	6.2 (17.49)	10.8 (21.62)	7.6 (17.34)	
Median	1.0	2.0	1.0	2.0	
Min, Max	0, 76	0, 93	0, 84	0, 84	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ism-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	8	20	19	31	
Mean (StdDev)	7.6 (11.70)	3.7 (9.29)	14.4 (28.33)	4.3 (11.14)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 30	0, 42	0, 90	0, 58	
C4D1 CFB					
n	8	20	19	31	
LS Mean (StdErr) [2]	1.31 (3.896)	-2.55 (2.619)	2.16 (1.494)	-2.55 (1.323)	
95% CI [2]	-6.71, 9.33	-7.95, 2.84	-0.85, 5.16	-5.21, 0.11	
Difference (95% CI) in CFB [2]		-3.86 (-12.30, 4.58)		-4.71 (-8.32, -1.10)	
p-value [3]		0.355		0.012	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ism-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.5a
Summary of Mastocytosis in Skin by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	7	17	14	34	
Mean (StdDev)	9.0 (13.76)	3.9 (9.03)	11.5 (22.90)	5.3 (14.33)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 35	0, 38	0, 65	0, 65	
C7D1 CFB					
n	7	17	14	34	
LS Mean (StdErr) [2]	2.17 (4.745)	-3.69 (2.995)	0.95 (1.819)	-4.36 (1.307)	
95% CI [2]	-7.69, 12.04	-9.92, 2.54	-2.71, 4.61	-6.99, -1.73	
Difference (95% CI) in CFB [2]		-5.86 (-16.69, 4.96)		-5.31 (-9.52, -1.10)	
Hedges'G (95% CI) in CFB		-0.46 (-1.45, 0.44)		-0.71 (-1.40, -0.08)	
p-value [3]		0.273		0.015	
					0.984

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ism-a.sas Date: 15:59/07AUG2023

Table 35.2.11.4.1.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	6	15	31	59	
Mean (StdDev)	3.0 (3.29)	8.9 (22.86)	22.8 (32.23)	10.3 (20.67)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 7	0, 91	0, 92	0, 97	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-tryp-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	6	9	21	42	
Mean (StdDev)	3.3 (3.39)	2.6 (2.40)	25.8 (35.81)	9.2 (20.55)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 8	0, 8	0, 97	0, 86	
C4D1 CFB					
n	6	9	21	42	
LS Mean (StdErr) [2]	0.27 (0.355)	-0.45 (0.264)	0.10 (1.014)	-2.50 (0.717)	
95% CI [2]	-0.50, 1.05	-1.03, 0.12	-1.93, 2.13	-3.93, -1.06	
Difference (95% CI) in CFB [2]		-0.73 (-1.67, 0.22)		-2.60 (-5.04, -0.16)	
p-value [3]		0.120		0.037	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-tryp-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	5	12	16	39	
Mean (StdDev)	3.2 (3.49)	8.4 (22.97)	24.9 (37.79)	9.0 (19.42)	
Median	1.0	1.5	2.5	2.0	
Min, Max	0, 7	0, 81	0, 98	0, 84	
C7D1 CFB					
n	5	12	16	39	
LS Mean (StdErr) [2]	0.46 (1.138)	-2.01 (0.702)	0.95 (1.828)	-3.47 (1.226)	
95% CI [2]	-1.98, 2.90	-3.52, -0.51	-2.72, 4.62	-5.93, -1.01	
Difference (95% CI) in CFB [2]		-2.47 (-5.28, 0.33)		-4.42 (-8.74, -0.10)	
Hedges'G (95% CI) in CFB		-0.95 (-2.30, 0.09)		-0.58 (-1.21, 0.01)	
p-value [3]		0.080		0.045	
					0.605

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-tryp-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	6	15	31	59	
Mean (StdDev)	2.7 (2.58)	8.3 (23.00)	18.1 (28.11)	6.5 (12.18)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 7	0, 91	0, 91	0, 75	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-tryp-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	6	9	21	42	
Mean (StdDev)	2.7 (2.16)	1.7 (1.87)	21.1 (31.35)	6.0 (12.61)	
Median	2.5	2.0	2.0	1.0	
Min, Max	0, 6	0, 6	0, 85	0, 56	
C4D1 CFB					
n	6	9	21	42	
LS Mean (StdErr) [2]	0.12 (0.393)	-0.76 (0.292)	0.45 (1.518)	-1.43 (1.074)	
95% CI [2]	-0.74, 0.98	-1.39, -0.12	-2.58, 3.49	-3.58, 0.71	
Difference (95% CI) in CFB [2]		-0.88 (-1.93, 0.17)		-1.89 (-5.54, 1.76)	
p-value [3]		0.092		0.305	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-tryp-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	5	12	16	39	
Mean (StdDev)	2.6 (2.41)	8.2 (23.00)	19.8 (31.01)	4.0 (6.62)	
Median	2.0	1.5	2.5	2.0	
Min, Max	0, 6	0, 81	0, 93	0, 27	
C7D1 CFB					
n	5	12	16	39	
LS Mean (StdErr) [2]	0.38 (1.193)	-1.23 (0.735)	-1.24 (2.282)	-3.41 (1.531)	
95% CI [2]	-2.18, 2.93	-2.81, 0.35	-5.82, 3.34	-6.48, -0.34	
Difference (95% CI) in CFB [2]		-1.61 (-4.54, 1.33)		-2.17 (-7.57, 3.22)	
Hedges'G (95% CI) in CFB		-0.59 (-1.84, 0.47)		-0.23 (-0.83, 0.36)	
p-value [3]		0.261		0.423	
					0.917

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-tryp-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	6	15	31	57	
Mean (StdDev)	1.0 (0.89)	8.5 (25.12)	16.8 (27.80)	7.6 (19.07)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 2	0, 99	0, 92	0, 97	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-tryp-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	6	9	21	41	
Mean (StdDev)	0.8 (0.98)	1.0 (1.00)	17.4 (31.01)	6.2 (18.26)	
Median	0.5	1.0	1.0	1.0	
Min, Max	0, 2	0, 3	0, 97	0, 86	
C4D1 CFB					
n	6	9	21	41	
LS Mean (StdErr) [2]	-0.20 (0.405)	-0.89 (0.301)	0.39 (1.897)	-2.88 (1.365)	
95% CI [2]	-1.08, 0.69	-1.55, -0.24	-3.41, 4.18	-5.61, -0.15	
Difference (95% CI) in CFB [2]		-0.70 (-1.78, 0.38)		-3.27 (-7.85, 1.31)	
p-value [3]		0.184		0.158	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-tryp-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	5	12	16	39	
Mean (StdDev)	0.6 (0.89)	7.0 (20.81)	16.2 (28.35)	6.7 (18.95)	
Median	0.0	1.0	2.5	1.0	
Min, Max	0, 2	0, 73	0, 98	0, 84	
C7D1 CFB					
n	5	12	16	39	
LS Mean (StdErr) [2]	0.56 (2.992)	-3.04 (1.844)	-0.74 (2.612)	-2.96 (1.752)	
95% CI [2]	-5.85, 6.98	-6.99, 0.92	-5.98, 4.50	-6.47, 0.56	
Difference (95% CI) in CFB [2]		-3.60 (-10.97, 3.77)		-2.22 (-8.39, 3.96)	
Hedges'G (95% CI) in CFB		-0.53 (-1.77, 0.54)		-0.20 (-0.81, 0.39)	
p-value [3]		0.313		0.474	
					0.863

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-tryp-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	6	15	31	58	
Mean (StdDev)	3.2 (3.13)	8.7 (21.55)	21.2 (30.30)	9.2 (17.11)	
Median	2.0	3.0	3.0	2.5	
Min, Max	0, 7	0, 86	0, 88	0, 81	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-tryp-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	6	9	21	42	
Mean (StdDev)	3.5 (3.27)	2.8 (2.33)	23.2 (31.69)	8.1 (16.17)	
Median	2.5	3.0	3.0	2.0	
Min, Max	0, 8	0, 8	0, 78	0, 67	
C4D1 CFB					
n	6	9	21	42	
LS Mean (StdErr) [2]	0.09 (0.627)	-0.82 (0.466)	-0.62 (1.042)	-1.77 (0.737)	
95% CI [2]	-1.28, 1.46	-1.83, 0.20	-2.71, 1.46	-3.24, -0.29	
Difference (95% CI) in CFB [2]		-0.91 (-2.58, 0.76)		-1.14 (-3.65, 1.36)	
p-value [3]		0.259		0.366	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-tryp-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	5	12	16	39	
Mean (StdDev)	3.2 (3.49)	8.8 (24.72)	20.4 (31.69)	6.5 (10.22)	
Median	1.0	1.5	2.5	2.0	
Min, Max	0, 7	0, 87	0, 91	0, 40	
C7D1 CFB					
n	5	12	16	39	
LS Mean (StdErr) [2]	-0.05 (0.416)	-1.10 (0.257)	-1.72 (3.171)	-4.06 (2.127)	
95% CI [2]	-0.94, 0.85	-1.65, -0.55	-8.08, 4.64	-8.33, 0.21	
Difference (95% CI) in CFB [2]		-1.05 (-2.08, -0.02)		-2.34 (-9.83, 5.16)	
Hedges'G (95% CI) in CFB		-1.11 (-2.50, -0.06)		-0.18 (-0.78, 0.41)	
p-value [3]		0.046		0.534	
					0.857

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-tryp-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	6	15	31	58	
Mean (StdDev)	0.7 (0.82)	7.7 (21.27)	13.5 (22.65)	6.8 (16.32)	
Median	0.5	1.0	2.0	2.0	
Min, Max	0, 2	0, 84	0, 84	0, 93	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-tryp-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	6	9	21	42	
Mean (StdDev)	0.7 (0.52)	2.0 (1.73)	15.8 (27.02)	4.5 (11.37)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 1	0, 5	0, 90	0, 58	
C4D1 CFB					
n	6	9	21	42	
LS Mean (StdErr) [2]	0.04 (0.610)	-0.33 (0.453)	1.70 (1.828)	-3.69 (1.293)	
95% CI [2]	-1.29, 1.36	-1.31, 0.66	-1.96, 5.35	-6.28, -1.11	
Difference (95% CI) in CFB [2]		-0.36 (-1.99, 1.26)		-5.39 (-9.79, -0.99)	
p-value [3]		0.634		0.017	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-tryp-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.6a
Summary of Mastocytosis in Skin by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	5	12	16	39	
Mean (StdDev)	0.6 (0.55)	5.7 (14.99)	13.8 (22.08)	4.5 (12.16)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 1	0, 53	0, 65	0, 65	
C7D1 CFB					
n	5	12	16	39	
LS Mean (StdErr) [2]	1.34 (3.538)	-3.35 (2.181)	1.21 (2.188)	-4.52 (1.468)	
95% CI [2]	-6.25, 8.93	-8.03, 1.33	-3.18, 5.60	-7.47, -1.58	
Difference (95% CI) in CFB [2]		-4.69 (-13.41, 4.03)		-5.73 (-10.91, -0.56)	
Hedges'G (95% CI) in CFB		-0.58 (-1.83, 0.48)		-0.62 (-1.26, -0.04)	
p-value [3]		0.268		0.030	
					0.707

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-tryp-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.7a
Summary of Mastocytosis in Skin by ECOG Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	36	70	1	4	
Mean (StdDev)	20.1 (30.66)	9.3 (19.74)	3.0 (-)	23.3 (38.66)	
Median	2.5	2.0	3.0	5.5	
Min, Max	0, 92	0, 97	3, 3	1, 81	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ecog-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.7a
Summary of Mastocytosis in Skin by ECOG Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	26	48	1	3	
Mean (StdDev)	21.5 (33.30)	6.6 (15.60)	3.0 (-)	30.3 (48.27)	
Median	3.0	2.0	3.0	5.0	
Min, Max	0, 97	0, 80	3, 3	0, 86	
C4D1 CFB					
n	26	48	1	3	
LS Mean (StdErr) [2]	0.43 (0.907)	-1.86 (0.722)	-1.25 (7.462)	-0.75 (3.897)	
95% CI [2]	-1.38, 2.23	-3.30, -0.41	-96.07, 93.57	-50.27, 48.77	
Difference (95% CI) in CFB [2]		-2.28 (-4.32, -0.24)		0.50 (-98.54, 99.54)	
p-value [3]		0.029		0.959	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ecog-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.7a
Summary of Mastocytosis in Skin by ECOG Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	20	48	1	3	
Mean (StdDev)	20.6 (34.76)	7.6 (17.55)	3.0 (-)	29.0 (46.81)	
Median	1.5	1.5	3.0	4.0	
Min, Max	0, 98	0, 84	3, 3	0, 83	
C7D1 CFB					
n	20	48	1	3	
LS Mean (StdErr) [2]	1.10 (1.564)	-2.98 (1.084)	0.00 (3.512)	-1.33 (2.028)	
95% CI [2]	-2.03, 4.22	-5.14, -0.81	-15.11, 15.11	-10.06, 7.39	
Difference (95% CI) in CFB [2]		-4.07 (-7.58, -0.57)		-1.33 (-18.78, 16.11)	
Hedges'G (95% CI) in CFB		-0.55 (-1.10, -0.03)		NE	
p-value [3]		0.023		0.774	
					0.724

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ecog-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.7a
Summary of Mastocytosis in Skin by ECOG Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	36	70	1	4	
Mean (StdDev)	16.0 (26.57)	6.8 (15.16)	1.0 (-)	7.0 (7.70)	
Median	3.0	2.0	1.0	5.5	
Min, Max	0, 91	0, 91	1, 1	0, 17	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ecog-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.7a
Summary of Mastocytosis in Skin by ECOG Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	26	48	1	3	
Mean (StdDev)	17.6 (29.00)	4.5 (10.28)	2.0 (-)	17.0 (25.24)	
Median	2.5	1.0	2.0	5.0	
Min, Max	0, 85	0, 56	2, 2	0, 46	
C4D1 CFB					
n	26	48	1	3	
LS Mean (StdErr) [2]	0.52 (1.132)	-1.65 (0.902)	-6.25 (27.362)	5.25 (14.289)	
95% CI [2]	-1.73, 2.78	-3.45, 0.14	-353.92, 341.42	-176.31, 186.81	
Difference (95% CI) in CFB [2]		-2.18 (-4.73, 0.37)		11.50 (-351.63, 374.63)	
p-value [3]		0.093		0.756	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ecog-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.7a
Summary of Mastocytosis in Skin by ECOG Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	20	48	1	3	
Mean (StdDev)	16.3 (28.47)	4.7 (12.42)	3.0 (-)	9.3 (12.86)	
Median	2.0	1.5	3.0	4.0	
Min, Max	0, 93	0, 81	3, 3	0, 24	
C7D1 CFB					
n	20	48	1	3	
LS Mean (StdErr) [2]	-0.35 (1.915)	-2.50 (1.328)	2.00 (6.028)	0.67 (3.480)	
95% CI [2]	-4.17, 3.48	-5.16, 0.15	-23.94, 27.94	-14.31, 15.64	
Difference (95% CI) in CFB [2]		-2.15 (-6.44, 2.14)		-1.33 (-31.28, 28.61)	
Hedges'G (95% CI) in CFB		-0.24 (-0.78, 0.29)		NE	
p-value [3]		0.320		0.866	
					0.931

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ecog-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.7a
Summary of Mastocytosis in Skin by ECOG Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	36	68	1	4	
Mean (StdDev)	14.6 (26.36)	6.9 (18.80)	3.0 (-)	21.5 (39.68)	
Median	1.5	1.0	3.0	2.0	
Min, Max	0, 92	0, 99	3, 3	1, 81	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ecog-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.7a
Summary of Mastocytosis in Skin by ECOG Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	26	47	1	3	
Mean (StdDev)	14.1 (28.56)	3.7 (12.21)	3.0 (-)	29.0 (49.37)	
Median	1.0	1.0	3.0	1.0	
Min, Max	0, 97	0, 80	3, 3	0, 86	
C4D1 CFB					
n	26	47	1	3	
LS Mean (StdErr) [2]	0.66 (1.699)	-2.33 (1.363)	-1.25 (5.804)	0.25 (3.031)	
95% CI [2]	-2.73, 4.05	-5.05, 0.39	-75.00, 72.50	-38.26, 38.76	
Difference (95% CI) in CFB [2]		-2.99 (-6.82, 0.85)		1.50 (-75.53, 78.53)	
p-value [3]		0.125		0.846	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ecog-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.7a
Summary of Mastocytosis in Skin by ECOG Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	20	48	1	3	
Mean (StdDev)	13.0 (26.04)	5.5 (16.27)	3.0 (-)	28.0 (47.63)	
Median	1.0	1.0	3.0	1.0	
Min, Max	0, 98	0, 84	3, 3	0, 83	
C7D1 CFB					
n	20	48	1	3	
LS Mean (StdErr) [2]	-0.49 (2.318)	-3.05 (1.607)	0.00 (2.082)	-0.33 (1.202)	
95% CI [2]	-5.12, 4.14	-6.26, 0.16	-8.96, 8.96	-5.50, 4.84	
Difference (95% CI) in CFB [2]		-2.56 (-7.75, 2.63)		-0.33 (-10.68, 10.01)	
Hedges'G (95% CI) in CFB		-0.23 (-0.77, 0.29)		NE	
p-value [3]		0.328		0.902	
					0.846

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ecog-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.7a
Summary of Mastocytosis in Skin by ECOG Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	36	69	1	4	
Mean (StdDev)	18.7 (28.78)	8.9 (18.08)	3.0 (-)	12.5 (17.37)	
Median	2.5	3.0	3.0	5.5	
Min, Max	0, 88	0, 86	3, 3	1, 38	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ecog-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.7a
Summary of Mastocytosis in Skin by ECOG Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	26	48	1	3	
Mean (StdDev)	19.5 (29.46)	6.6 (14.30)	3.0 (-)	16.0 (23.52)	
Median	3.0	2.0	3.0	5.0	
Min, Max	0, 78	0, 67	3, 3	0, 43	
C4D1 CFB					
n	26	48	1	3	
LS Mean (StdErr) [2]	-0.15 (0.929)	-1.34 (0.740)	-1.25 (7.462)	-0.75 (3.897)	
95% CI [2]	-2.00, 1.71	-2.82, 0.13	-96.07, 93.57	-50.27, 48.77	
Difference (95% CI) in CFB [2]		-1.20 (-3.29, 0.90)		0.50 (-98.54, 99.54)	
p-value [3]		0.259		0.959	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ecog-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.7a
Summary of Mastocytosis in Skin by ECOG Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	20	48	1	3	
Mean (StdDev)	17.0 (29.07)	6.7 (14.55)	3.0 (-)	12.3 (18.82)	
Median	1.5	1.5	3.0	3.0	
Min, Max	0, 91	0, 87	3, 3	0, 34	
C7D1 CFB					
n	20	48	1	3	
LS Mean (StdErr) [2]	-0.68 (2.686)	-2.66 (1.863)	0.00 (2.517)	-3.67 (1.453)	
95% CI [2]	-6.05, 4.68	-6.38, 1.06	-10.83, 10.83	-9.92, 2.58	
Difference (95% CI) in CFB [2]		-1.98 (-7.99, 4.04)		-3.67 (-16.17, 8.84)	
Hedges'G (95% CI) in CFB		-0.15 (-0.69, 0.37)		NE	
p-value [3]		0.514		0.334	
					0.899

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ecog-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.7a
Summary of Mastocytosis in Skin by ECOG Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	36	69	1	4	
Mean (StdDev)	11.7 (21.45)	6.2 (15.64)	1.0 (-)	20.8 (36.88)	
Median	1.0	2.0	1.0	3.0	
Min, Max	0, 84	0, 93	1, 1	1, 76	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ecog-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.7a
Summary of Mastocytosis in Skin by ECOG Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	26	48	1	3	
Mean (StdDev)	12.8 (24.92)	3.1 (7.13)	1.0 (-)	20.0 (32.92)	
Median	1.0	1.0	1.0	2.0	
Min, Max	0, 90	0, 42	1, 1	0, 58	
C4D1 CFB					
n	26	48	1	3	
LS Mean (StdErr) [2]	1.51 (1.619)	-2.56 (1.290)	4.75 (12.437)	-5.75 (6.495)	
95% CI [2]	-1.72, 4.74	-5.13, 0.01	-153.28, 162.78	-88.28, 76.78	
Difference (95% CI) in CFB [2]		-4.07 (-7.71, -0.42)		-10.50 (-175.56, 154.56)	
p-value [3]		0.029		0.567	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ecog-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.7a
Summary of Mastocytosis in Skin by ECOG Status
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	20	48	1	3	
Mean (StdDev)	11.2 (20.37)	3.8 (9.65)	1.0 (-)	21.7 (37.53)	
Median	1.0	1.0	1.0	0.0	
Min, Max	0, 65	0, 53	1, 1	0, 65	
C7D1 CFB					
n	20	48	1	3	
LS Mean (StdErr) [2]	1.05 (2.042)	-4.07 (1.416)	0.00 (5.033)	-5.67 (2.906)	
95% CI [2]	-3.03, 5.13	-6.90, -1.24	-21.66, 21.66	-18.17, 6.84	
Difference (95% CI) in CFB [2]		-5.12 (-9.69, -0.55)		-5.67 (-30.67, 19.34)	
Hedges'G (95% CI) in CFB		-0.53 (-1.08, -0.00)		NE	
p-value [3]		0.029		0.432	
					0.957

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-ecog-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	5	33	69	
Mean (StdDev)	32.0 (40.41)	21.2 (39.19)	18.1 (29.37)	9.2 (19.29)	
Median	14.5	3.0	2.0	2.0	
Min, Max	7, 92	1, 91	0, 91	0, 97	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-thpy-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	4	2	23	49	
Mean (StdDev)	33.0 (42.92)	3.0 (1.41)	18.7 (31.50)	8.2 (19.17)	
Median	14.0	3.0	2.0	2.0	
Min, Max	7, 97	2, 4	0, 85	0, 86	
C4D1 CFB					
n	4	2	23	49	
LS Mean (StdErr) [2]	-0.25 (2.332)	-7.75 (5.214)	0.26 (0.986)	-1.68 (0.732)	
95% CI [2]	-10.28, 9.78	-30.18, 14.68	-1.71, 2.23	-3.14, -0.22	
Difference (95% CI) in CFB [2]		-7.50 (-27.57, 12.57)		-1.94 (-4.10, 0.22)	
p-value [3]		0.249		0.078	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-thpy-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Most Affected Region

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	4	17	47	
Mean (StdDev)	33.8 (43.19)	21.0 (40.01)	16.4 (32.29)	7.9 (17.88)	
Median	15.0	1.5	1.0	2.0	
Min, Max	7, 98	0, 81	0, 93	0, 84	
C7D1 CFB					
n	4	4	17	47	
LS Mean (StdErr) [2]	0.10 (1.706)	-9.30 (2.606)	0.98 (1.736)	-2.59 (1.128)	
95% CI [2]	-4.64, 4.84	-16.53, -2.07	-2.49, 4.45	-4.84, -0.33	
Difference (95% CI) in CFB [2]		-9.40 (-17.13, -1.67)		-3.57 (-7.36, 0.22)	
Hedges'G (95% CI) in CFB		-1.85 (-4.93, -0.46)		-0.46 (-1.05, 0.09)	
p-value [3]		0.028		0.065	
					0.576

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-thpy-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	5	33	69	
Mean (StdDev)	29.5 (39.92)	20.0 (39.77)	13.9 (24.54)	5.9 (11.37)	
Median	11.5	3.0	1.0	2.0	
Min, Max	6, 89	0, 91	0, 91	0, 75	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-thpy-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	4	2	23	49	
Mean (StdDev)	26.5 (35.26)	1.0 (0.00)	15.3 (27.89)	5.4 (11.77)	
Median	10.5	1.0	2.0	2.0	
Min, Max	6, 79	1, 1	0, 85	0, 56	
C4D1 CFB					
n	4	2	23	49	
LS Mean (StdErr) [2]	-0.75 (1.862)	7.25 (4.165)	0.76 (1.455)	-1.32 (1.080)	
95% CI [2]	-8.76, 7.26	-10.67, 25.17	-2.14, 3.67	-3.47, 0.84	
Difference (95% CI) in CFB [2]		8.00 (-8.03, 24.03)		-2.08 (-5.27, 1.11)	
p-value [3]		0.165		0.198	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-thpy-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Thigh

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	4	17	47	
Mean (StdDev)	22.0 (25.21)	20.8 (40.17)	14.2 (29.00)	3.7 (6.12)	
Median	11.5	1.0	1.0	2.0	
Min, Max	6, 59	0, 81	0, 93	0, 27	
C7D1 CFB					
n	4	4	17	47	
LS Mean (StdErr) [2]	-5.90 (5.789)	7.70 (8.843)	1.21 (1.952)	-2.38 (1.268)	
95% CI [2]	-21.97, 10.17	-16.85, 32.25	-2.70, 5.11	-4.92, 0.15	
Difference (95% CI) in CFB [2]		13.60 (-12.65, 39.85)		-3.59 (-7.86, 0.67)	
Hedges'G (95% CI) in CFB		0.79 (-0.67, 2.99)		-0.42 (-1.00, 0.14)	
p-value [3]		0.224		0.097	
					0.164

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-thpy-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	5	33	67	
Mean (StdDev)	29.8 (42.24)	21.4 (43.39)	12.4 (23.73)	6.7 (17.70)	
Median	12.5	2.0	1.0	1.0	
Min, Max	2, 92	1, 99	0, 86	0, 97	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-thpy-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	4	2	23	48	
Mean (StdDev)	30.8 (44.69)	1.0 (0.00)	10.7 (24.45)	5.4 (16.95)	
Median	12.0	1.0	1.0	1.0	
Min, Max	2, 97	1, 1	0, 93	0, 86	
C4D1 CFB					
n	4	2	23	48	
LS Mean (StdErr) [2]	-0.25 (0.968)	-6.75 (2.165)	0.57 (1.857)	-2.16 (1.387)	
95% CI [2]	-4.42, 3.92	-16.07, 2.57	-3.14, 4.28	-4.93, 0.61	
Difference (95% CI) in CFB [2]		-6.50 (-14.83, 1.83)		-2.73 (-6.81, 1.35)	
p-value [3]		0.078		0.186	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-thpy-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Back Torso

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	4	17	47	
Mean (StdDev)	31.5 (45.00)	19.3 (35.84)	8.0 (17.89)	5.7 (17.38)	
Median	13.0	1.5	1.0	1.0	
Min, Max	2, 98	1, 73	0, 70	0, 84	
C7D1 CFB					
n	4	4	17	47	
LS Mean (StdErr) [2]	-2.65 (2.941)	-17.05 (4.492)	-0.66 (2.485)	-2.20 (1.615)	
95% CI [2]	-10.81, 5.51	-29.52, -4.58	-5.63, 4.31	-5.43, 1.03	
Difference (95% CI) in CFB [2]		-14.40 (-27.73, -1.07)		-1.54 (-6.97, 3.89)	
Hedges'G (95% CI) in CFB		-1.65 (-4.54, -0.26)		-0.14 (-0.71, 0.42)	
p-value [3]		0.040		0.573	
					0.340

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-thpy-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	5	33	68	
Mean (StdDev)	30.5 (38.63)	19.8 (37.21)	16.8 (27.43)	8.3 (15.95)	
Median	13.5	1.0	2.0	3.0	
Min, Max	7, 88	1, 86	0, 82	0, 81	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-thpy-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	4	2	23	49	
Mean (StdDev)	25.0 (27.07)	3.0 (1.41)	17.8 (29.83)	7.3 (15.09)	
Median	14.0	3.0	2.0	2.0	
Min, Max	7, 65	2, 4	0, 78	0, 67	
C4D1 CFB					
n	4	2	23	49	
LS Mean (StdErr) [2]	0.25 (2.165)	20.75 (4.841)	0.48 (0.789)	-1.43 (0.586)	
95% CI [2]	-9.07, 9.57	-0.08, 41.58	-1.09, 2.06	-2.60, -0.26	
Difference (95% CI) in CFB [2]		20.50 (1.87, 39.13)		-1.91 (-3.64, -0.18)	
p-value [3]		0.042		0.031	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-thpy-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Thigh

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	4	17	47	
Mean (StdDev)	16.3 (9.60)	22.5 (43.01)	16.4 (31.59)	5.7 (9.50)	
Median	15.0	1.5	1.0	2.0	
Min, Max	7, 28	0, 87	0, 91	0, 40	
C7D1 CFB					
n	4	4	17	47	
LS Mean (StdErr) [2]	-7.65 (8.570)	26.95 (13.091)	1.91 (2.267)	-3.23 (1.473)	
95% CI [2]	-31.44, 16.14	-9.40, 63.30	-2.63, 6.44	-6.18, -0.29	
Difference (95% CI) in CFB [2]		34.60 (-4.26, 73.46)		-5.14 (-10.09, -0.18)	
Hedges'G (95% CI) in CFB		1.36 (-0.03, 4.00)		-0.51 (-1.10, 0.04)	
p-value [3]		0.069		0.042	
					0.031

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-thpy-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	5	33	68	
Mean (StdDev)	21.8 (25.32)	18.0 (36.95)	10.2 (20.78)	6.2 (15.17)	
Median	14.5	1.0	1.0	2.0	
Min, Max	1, 57	0, 84	0, 84	0, 93	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-thpy-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	4	2	23	49	
Mean (StdDev)	28.0 (37.74)	1.0 (0.00)	9.7 (21.58)	4.2 (10.55)	
Median	14.0	1.0	1.0	1.0	
Min, Max	1, 83	1, 1	0, 90	0, 58	
C4D1 CFB					
n	4	2	23	49	
LS Mean (StdErr) [2]	-0.25 (1.561)	-27.75 (3.491)	1.06 (1.674)	-2.49 (1.243)	
95% CI [2]	-6.97, 6.47	-42.77, -12.73	-2.28, 4.40	-4.97, -0.01	
Difference (95% CI) in CFB [2]		-27.50 (-40.94, -14.06)		-3.54 (-7.21, 0.13)	
p-value [3]		0.013		0.058	

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-thpy-a.sas Date: 16:00/07AUG2023

Table 35.2.11.4.1.8a
Summary of Mastocytosis in Skin by Prior TKI Therapy
Safety Population, Part 2 (Part 2 Baseline)

Affected Surface Area (%): Front Torso

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	4	17	47	
Mean (StdDev)	23.3 (29.10)	13.8 (26.17)	7.7 (17.06)	4.0 (11.13)	
Median	13.5	1.0	1.0	1.0	
Min, Max	1, 65	0, 53	0, 64	0, 65	
C7D1 CFB					
n	4	4	17	47	
LS Mean (StdErr) [2]	-3.80 (3.477)	-21.60 (5.311)	1.44 (2.095)	-3.20 (1.361)	
95% CI [2]	-13.45, 5.85	-36.35, -6.85	-2.75, 5.63	-5.92, -0.47	
Difference (95% CI) in CFB [2]		-17.80 (-33.56, -2.04)		-4.63 (-9.21, -0.06)	
Hedges'G (95% CI) in CFB		-1.72 (-4.68, -0.34)		-0.50 (-1.09, 0.06)	
p-value [3]		0.035		0.047	
					0.362

Abbreviations: CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.4.9
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mast-skin-g-saf-thpy-a.sas Date: 16:00/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	58.34 (17.271)	58.00 (15.956)	52.95 (16.875)	50.51 (16.218)	
Median	60.19	57.41	54.63	44.44	
Min, Max	22.2, 97.2	13.9, 98.1	27.8, 83.3	28.7, 70.4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	50.14 (17.318)	45.31 (17.997)	45.29 (15.480)	37.35 (16.316)	
Median	52.78	44.44	40.74	40.74	
Min, Max	15.7, 92.6	6.5, 90.7	16.7, 76.9	6.5, 58.3	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	-6.63 (1.789)	-11.70 (1.289)	-11.59 (3.834)	-19.53 (4.863)	
95% CI [2]	-10.16, -3.10	-14.25, -9.16	-19.71, -3.46	-29.84, -9.23	
Difference (95% CI) in CFB [2]		-5.07 (-8.96, -1.19)		-7.95 (-15.53, -0.37)	
p-value [3]		0.011		0.041	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	118	10	9	
Mean (StdDev)	49.30 (19.819)	41.77 (18.518)	44.07 (17.785)	27.67 (13.333)	
Median	50.00	38.43	41.20	27.78	
Min, Max	10.2, 88.0	1.9, 93.5	17.6, 81.5	1.9, 48.1	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-8.14 (2.113)	-14.90 (1.512)	-10.55 (6.698)	-27.52 (8.433)	
95% CI [2]	-12.31, -3.97	-17.88, -11.91	-24.82, 3.73	-45.50, -9.55	
Difference (95% CI) in CFB [2]		-6.76 (-11.36, -2.16)		-16.98 (-30.35, -3.60)	
p-value [3]		0.004		0.016	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	48.72 (19.347)	42.04 (20.133)	50.79 (19.536)	26.65 (16.806)	
Median	47.22	40.28	44.44	23.15	
Min, Max	11.1, 80.6	2.8, 90.7	29.6, 87.0	1.9, 49.1	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-9.27 (2.331)	-15.85 (1.654)	-6.20 (7.112)	-28.69 (9.483)	
95% CI [2]	-13.88, -4.67	-19.12, -12.59	-21.70, 9.30	-49.35, -8.03	
Difference (95% CI) in CFB [2]		-6.58 (-11.56, -1.61)		-22.49 (-39.78, -5.20)	
p-value [3]		0.010		0.015	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	116	9	8	
Mean (StdDev)	46.96 (20.910)	40.08 (20.169)	52.26 (17.391)	21.99 (13.287)	
Median	46.43	36.11	51.85	22.69	
Min, Max	10.2, 88.0	4.6, 93.5	29.6, 78.7	3.7, 44.4	
C5D1 CFB					
n	53	110	9	8	
LS Mean (StdErr) [2]	-10.29 (2.382)	-17.76 (1.743)	-6.81 (9.456)	-33.88 (12.258)	
95% CI [2]	-15.00, -5.59	-21.20, -14.32	-27.23, 13.62	-60.36, -7.39	
Difference (95% CI) in CFB [2]		-7.47 (-12.64, -2.30)		-27.07 (-47.71, -6.44)	
p-value [3]		0.005		0.014	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	49.25 (20.741)	39.21 (21.631)	48.96 (14.322)	22.94 (12.711)	
Median	50.00	36.11	45.83	20.37	
Min, Max	12.0, 89.8	2.8, 92.6	32.4, 75.9	6.5, 48.1	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-7.62 (2.563)	-18.21 (1.826)	-9.81 (7.130)	-33.99 (9.597)	
95% CI [2]	-12.68, -2.56	-21.81, -14.60	-25.21, 5.60	-54.72, -13.26	
Difference (95% CI) in CFB [2]		-10.59 (-16.15, -5.03)		-24.18 (-41.18, -7.19)	
p-value [3]		<0.001		0.009	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	46.97 (21.720)	38.87 (21.960)	47.50 (17.151)	26.85 (11.991)	
Median	48.61	36.11	42.59	27.31	
Min, Max	12.0, 89.8	0.9, 92.6	21.3, 79.6	11.1, 50.9	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-8.13 (2.681)	-16.32 (1.895)	-8.49 (8.708)	-31.33 (11.520)	
95% CI [2]	-13.43, -2.84	-20.06, -12.57	-27.16, 10.19	-56.03, -6.62	
Difference (95% CI) in CFB [2]		-8.18 (-13.93, -2.44)		-22.84 (-41.52, -4.16)	
Hedges'G (95% CI) in CFB		-0.41 (-0.76, -0.08)		-0.73 (-1.88, 0.21)	
p-value [3]		0.006		0.020	
					0.132

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	66.42 (16.883)	65.63 (15.931)	51.01 (15.776)	58.33 (17.403)	
Median	63.89	68.06	52.78	61.11	
Min, Max	13.9, 100.0	16.7, 97.2	30.6, 72.2	22.2, 80.6	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	57.25 (18.853)	52.52 (18.332)	45.20 (13.152)	45.06 (19.133)	
Median	56.94	52.78	41.67	52.78	
Min, Max	11.1, 100.0	8.3, 94.4	27.8, 66.7	11.1, 69.4	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	-7.82 (2.051)	-12.22 (1.478)	-12.40 (5.988)	-22.34 (7.595)	
95% CI [2]	-11.87, -3.77	-15.14, -9.30	-25.09, 0.30	-38.44, -6.23	
Difference (95% CI) in CFB [2]		-4.40 (-8.85, 0.05)		-9.94 (-21.77, 1.90)	
p-value [3]		0.053		0.094	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	119	10	9	
Mean (StdDev)	56.24 (21.332)	49.03 (19.926)	44.17 (16.483)	37.65 (17.017)	
Median	55.56	47.22	37.50	44.44	
Min, Max	11.1, 100.0	5.6, 95.8	27.8, 69.4	2.8, 55.6	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-9.36 (2.430)	-15.30 (1.738)	-8.41 (5.872)	-24.61 (7.394)	
95% CI [2]	-14.16, -4.57	-18.74, -11.87	-20.93, 4.11	-40.37, -8.85	
Difference (95% CI) in CFB [2]		-5.94 (-11.23, -0.65)		-16.20 (-27.93, -4.48)	
p-value [3]		0.028		0.010	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	56.08 (22.939)	49.98 (20.919)	50.40 (16.929)	31.79 (16.024)	
Median	61.11	50.00	44.44	33.33	
Min, Max	11.1, 97.2	5.6, 94.4	27.8, 77.8	5.6, 52.8	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-10.00 (2.645)	-14.72 (1.877)	-1.99 (7.947)	-27.50 (10.595)	
95% CI [2]	-15.22, -4.78	-18.42, -11.01	-19.30, 15.33	-50.58, -4.41	
Difference (95% CI) in CFB [2]		-4.72 (-10.36, 0.93)		-25.51 (-44.82, -6.19)	
p-value [3]		0.101		0.014	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	116	9	8	
Mean (StdDev)	55.31 (23.013)	48.12 (21.015)	55.86 (15.741)	28.47 (17.615)	
Median	61.11	47.22	47.22	30.56	
Min, Max	11.1, 94.4	5.6, 100.0	41.7, 83.3	2.8, 58.3	
C5D1 CFB					
n	53	110	9	8	
LS Mean (StdErr) [2]	-10.73 (2.576)	-17.00 (1.885)	-1.59 (9.633)	-34.65 (12.486)	
95% CI [2]	-15.82, -5.64	-20.72, -13.27	-22.40, 19.22	-61.63, -7.68	
Difference (95% CI) in CFB [2]		-6.27 (-11.86, -0.68)		-33.06 (-54.08, -12.04)	
p-value [3]		0.028		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	56.22 (22.228)	46.09 (22.709)	50.00 (11.691)	30.25 (13.710)	
Median	55.56	44.44	50.00	25.00	
Min, Max	16.7, 97.2	2.8, 97.2	33.3, 63.9	11.1, 52.8	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-8.21 (2.821)	-17.66 (2.009)	-9.84 (6.920)	-35.07 (9.313)	
95% CI [2]	-13.78, -2.64	-21.62, -13.69	-24.79, 5.11	-55.19, -14.95	
Difference (95% CI) in CFB [2]		-9.45 (-15.57, -3.33)		-25.23 (-41.73, -8.74)	
p-value [3]		0.003		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	54.17 (22.069)	47.01 (22.486)	47.50 (13.637)	32.99 (11.253)	
Median	55.56	41.67	47.22	30.56	
Min, Max	13.9, 97.2	0.0, 100.0	25.0, 66.7	22.2, 58.3	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-9.32 (2.908)	-15.85 (2.056)	-7.67 (8.904)	-31.02 (11.780)	
95% CI [2]	-15.07, -3.58	-19.91, -11.79	-26.77, 11.43	-56.28, -5.75	
Difference (95% CI) in CFB [2]		-6.53 (-12.76, -0.29)		-23.35 (-42.44, -4.25)	
Hedges'G (95% CI) in CFB		-0.30 (-0.64, 0.03)		-0.73 (-1.88, 0.21)	
p-value [3]		0.040		0.020	
					0.075

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	55.87 (22.618)	56.55 (21.162)	52.53 (24.766)	45.99 (16.846)	
Median	58.33	56.94	47.22	38.89	
Min, Max	13.9, 97.2	5.6, 100.0	13.9, 94.4	22.2, 72.2	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	48.28 (22.239)	44.01 (23.733)	42.68 (24.447)	31.17 (18.309)	
Median	50.00	40.28	33.33	36.11	
Min, Max	5.6, 91.7	0.0, 100.0	2.8, 88.9	2.8, 58.3	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	-6.17 (2.276)	-11.37 (1.639)	-11.79 (5.254)	-20.23 (6.663)	
95% CI [2]	-10.66, -1.68	-14.60, -8.13	-22.93, -0.65	-34.36, -6.11	
Difference (95% CI) in CFB [2]		-5.20 (-10.13, -0.26)		-8.45 (-18.83, 1.94)	
p-value [3]		0.039		0.104	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	118	10	9	
Mean (StdDev)	48.64 (23.798)	41.03 (23.191)	41.67 (23.859)	17.28 (15.009)	
Median	47.22	40.28	37.50	13.89	
Min, Max	5.6, 88.9	0.0, 100.0	8.3, 88.9	0.0, 44.4	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-6.77 (2.529)	-14.38 (1.809)	-12.65 (7.665)	-36.73 (9.651)	
95% CI [2]	-11.76, -1.77	-17.95, -10.81	-28.99, 3.68	-57.30, -16.16	
Difference (95% CI) in CFB [2]		-7.62 (-13.12, -2.11)		-24.07 (-39.38, -8.77)	
p-value [3]		0.007		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	46.54 (22.750)	40.76 (24.536)	45.24 (30.417)	22.53 (19.516)	
Median	47.22	37.50	36.11	13.89	
Min, Max	2.8, 88.9	0.0, 97.2	11.1, 94.4	0.0, 50.0	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-8.62 (2.833)	-15.35 (2.010)	-11.25 (8.897)	-30.89 (11.863)	
95% CI [2]	-14.21, -3.02	-19.31, -11.38	-30.63, 8.14	-56.74, -5.04	
Difference (95% CI) in CFB [2]		-6.73 (-12.77, -0.68)		-19.64 (-41.27, 1.98)	
p-value [3]		0.029		0.071	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	54	117	9	8	
Mean (StdDev)	44.65 (24.556)	38.40 (24.592)	46.60 (23.520)	15.97 (13.988)	
Median	45.83	36.11	41.67	11.11	
Min, Max	0.0, 94.4	0.0, 100.0	16.7, 83.3	0.0, 38.9	
C5D1 CFB					
n	52	111	9	8	
LS Mean (StdErr) [2]	-9.46 (2.942)	-18.10 (2.136)	-11.55 (12.386)	-38.55 (16.055)	
95% CI [2]	-15.27, -3.65	-22.32, -13.88	-38.31, 15.21	-73.24, -3.87	
Difference (95% CI) in CFB [2]		-8.64 (-15.03, -2.26)		-27.01 (-54.03, 0.02)	
p-value [3]		0.008		0.050	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	48.71 (24.394)	37.73 (25.892)	45.83 (19.754)	16.98 (15.924)	
Median	50.00	33.33	38.89	11.11	
Min, Max	0.0, 94.4	0.0, 100.0	25.0, 86.1	0.0, 47.2	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-6.16 (3.032)	-18.54 (2.160)	-10.46 (9.333)	-33.80 (12.561)	
95% CI [2]	-12.14, -0.17	-22.81, -14.28	-30.62, 9.70	-60.93, -6.66	
Difference (95% CI) in CFB [2]		-12.38 (-18.96, -5.81)		-23.33 (-45.58, -1.09)	
p-value [3]		<0.001		0.041	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	46.05 (26.611)	36.69 (25.959)	43.33 (23.322)	20.83 (14.164)	
Median	47.22	33.33	43.06	20.83	
Min, Max	0.0, 97.2	0.0, 100.0	11.1, 88.9	2.8, 47.2	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-6.58 (3.186)	-16.58 (2.253)	-13.86 (10.108)	-39.12 (13.372)	
95% CI [2]	-12.87, -0.28	-21.03, -12.13	-35.54, 7.82	-67.80, -10.44	
Difference (95% CI) in CFB [2]		-10.01 (-16.84, -3.18)		-25.26 (-46.94, -3.58)	
Hedges'G (95% CI) in CFB		-0.42 (-0.77, -0.09)		-0.69 (-1.84, 0.24)	
p-value [3]		0.004		0.025	
					0.256

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	48.86 (23.693)	49.93 (23.315)	49.62 (18.861)	43.52 (25.096)	
Median	45.83	50.00	54.17	50.00	
Min, Max	0.0, 100.0	0.0, 100.0	20.8, 79.2	8.3, 75.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	41.09 (22.410)	38.64 (24.406)	42.80 (22.212)	37.04 (26.471)	
Median	41.67	33.33	45.83	33.33	
Min, Max	0.0, 91.7	0.0, 100.0	4.2, 83.3	0.0, 79.2	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	-6.25 (2.223)	-11.10 (1.601)	-9.50 (7.034)	-10.04 (8.921)	
95% CI [2]	-10.64, -1.86	-14.26, -7.94	-24.41, 5.41	-28.96, 8.87	
Difference (95% CI) in CFB [2]		-4.85 (-9.67, -0.03)		-0.54 (-14.45, 13.36)	
p-value [3]		0.049		0.935	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	119	10	9	
Mean (StdDev)	38.95 (23.070)	34.50 (22.754)	45.42 (23.112)	23.61 (18.400)	
Median	37.50	33.33	47.92	25.00	
Min, Max	0.0, 87.5	0.0, 95.8	12.5, 91.7	0.0, 50.0	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-9.04 (2.448)	-15.27 (1.751)	-5.44 (8.175)	-20.02 (10.293)	
95% CI [2]	-13.88, -4.21	-18.73, -11.81	-22.86, 11.98	-41.96, 1.92	
Difference (95% CI) in CFB [2]		-6.23 (-11.56, -0.89)		-14.58 (-30.91, 1.74)	
p-value [3]		0.022		0.076	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	39.15 (23.787)	34.67 (24.419)	57.14 (20.229)	23.15 (24.395)	
Median	37.50	31.25	54.17	16.67	
Min, Max	0.0, 83.3	0.0, 95.8	29.2, 91.7	0.0, 58.3	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-10.80 (2.785)	-17.45 (1.976)	-2.25 (9.368)	-27.76 (12.491)	
95% CI [2]	-16.30, -5.30	-21.35, -13.55	-22.66, 18.17	-54.98, -0.55	
Difference (95% CI) in CFB [2]		-6.64 (-12.59, -0.70)		-25.52 (-48.29, -2.75)	
p-value [3]		0.029		0.031	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	117	9	8	
Mean (StdDev)	36.67 (24.075)	31.66 (24.160)	49.54 (23.427)	17.19 (17.878)	
Median	37.50	25.00	58.33	14.58	
Min, Max	0.0, 95.8	0.0, 91.7	4.2, 70.8	0.0, 41.7	
C5D1 CFB					
n	53	111	9	8	
LS Mean (StdErr) [2]	-12.11 (2.886)	-19.45 (2.104)	-5.67 (9.717)	-25.81 (12.596)	
95% CI [2]	-17.81, -6.41	-23.60, -15.29	-26.66, 15.32	-53.02, 1.40	
Difference (95% CI) in CFB [2]		-7.33 (-13.59, -1.08)		-20.14 (-41.34, 1.07)	
p-value [3]		0.022		0.061	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	39.20 (25.124)	31.67 (24.644)	48.96 (21.099)	18.52 (14.450)	
Median	35.42	29.17	45.83	16.67	
Min, Max	0.0, 100.0	0.0, 95.8	25.0, 79.2	0.0, 37.5	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-9.12 (3.020)	-19.83 (2.151)	-8.75 (8.772)	-34.03 (11.806)	
95% CI [2]	-15.09, -3.16	-24.08, -15.58	-27.70, 10.20	-59.53, -8.52	
Difference (95% CI) in CFB [2]		-10.71 (-17.26, -4.15)		-25.28 (-46.19, -4.37)	
p-value [3]		0.002		0.022	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	36.54 (25.878)	31.06 (26.423)	45.00 (24.280)	24.48 (17.171)	
Median	33.33	25.00	43.75	22.92	
Min, Max	0.0, 100.0	0.0, 95.8	12.5, 79.2	4.2, 45.8	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-9.29 (3.243)	-16.88 (2.293)	-2.53 (9.698)	-19.79 (12.829)	
95% CI [2]	-15.70, -2.88	-21.41, -12.35	-23.33, 18.27	-47.31, 7.72	
Difference (95% CI) in CFB [2]		-7.59 (-14.55, -0.64)		-17.26 (-38.06, 3.54)	
Hedges'G (95% CI) in CFB		-0.32 (-0.66, 0.02)		-0.49 (-1.59, 0.46)	
p-value [3]		0.033		0.097	
					0.316

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	60.96 (23.047)	55.56 (22.311)	66.67 (21.082)	54.63 (23.976)	
Median	66.67	58.33	75.00	50.00	
Min, Max	0.0, 100.0	0.0, 100.0	33.3, 91.7	25.0, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	52.59 (21.641)	40.95 (18.911)	58.33 (20.069)	33.33 (18.162)	
Median	50.00	41.67	58.33	25.00	
Min, Max	0.0, 91.7	0.0, 83.3	25.0, 83.3	16.7, 66.7	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	-5.46 (2.978)	-12.19 (2.146)	-12.70 (6.812)	-28.01 (8.640)	
95% CI [2]	-11.34, 0.42	-16.42, -7.95	-27.14, 1.74	-46.33, -9.70	
Difference (95% CI) in CFB [2]		-6.73 (-13.19, -0.26)		-15.31 (-28.78, -1.85)	
p-value [3]		0.041		0.028	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	119	10	9	
Mean (StdDev)	51.17 (23.169)	38.66 (19.670)	48.33 (19.165)	37.04 (23.611)	
Median	50.00	41.67	50.00	33.33	
Min, Max	0.0, 100.0	0.0, 91.7	25.0, 75.0	0.0, 83.3	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-7.19 (3.410)	-14.44 (2.440)	-20.83 (12.223)	-23.61 (15.390)	
95% CI [2]	-13.92, -0.46	-19.26, -9.63	-46.89, 5.22	-56.41, 9.19	
Difference (95% CI) in CFB [2]		-7.25 (-14.68, 0.17)		-2.78 (-27.19, 21.63)	
p-value [3]		0.056		0.812	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	52.36 (23.592)	36.74 (20.427)	55.95 (22.420)	30.56 (19.543)	
Median	50.00	33.33	66.67	25.00	
Min, Max	0.0, 100.0	0.0, 100.0	25.0, 83.3	0.0, 58.3	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-6.39 (3.625)	-17.54 (2.572)	-11.60 (12.202)	-27.51 (16.270)	
95% CI [2]	-13.55, 0.77	-22.62, -12.46	-38.19, 14.98	-62.95, 7.94	
Difference (95% CI) in CFB [2]		-11.15 (-18.89, -3.41)		-15.90 (-45.56, 13.75)	
p-value [3]		0.005		0.265	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	116	9	8	
Mean (StdDev)	49.70 (25.558)	36.85 (20.298)	63.89 (29.167)	30.21 (16.022)	
Median	50.00	33.33	75.00	25.00	
Min, Max	0.0, 100.0	0.0, 100.0	25.0, 91.7	16.7, 58.3	
C5D1 CFB					
n	53	110	9	8	
LS Mean (StdErr) [2]	-7.93 (3.602)	-16.26 (2.636)	-10.49 (9.037)	-33.64 (11.714)	
95% CI [2]	-15.04, -0.81	-21.47, -11.06	-30.02, 9.03	-58.95, -8.33	
Difference (95% CI) in CFB [2]		-8.34 (-16.15, -0.52)		-23.15 (-42.87, -3.43)	
p-value [3]		0.037		0.025	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	50.00 (24.390)	38.06 (22.603)	55.21 (29.188)	27.78 (20.412)	
Median	50.00	33.33	50.00	16.67	
Min, Max	0.0, 100.0	0.0, 91.7	16.7, 100.0	8.3, 66.7	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-7.64 (3.642)	-15.52 (2.594)	-9.86 (12.062)	-31.25 (16.235)	
95% CI [2]	-14.84, -0.45	-20.64, -10.40	-35.92, 16.20	-66.32, 3.82	
Difference (95% CI) in CFB [2]		-7.88 (-15.78, 0.02)		-21.39 (-50.14, 7.36)	
p-value [3]		0.051		0.132	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.1a
Change from Baseline in MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	49.04 (24.290)	36.55 (21.180)	65.00 (22.153)	31.25 (20.774)	
Median	50.00	33.33	66.67	25.00	
Min, Max	0.0, 100.0	0.0, 91.7	33.3, 100.0	8.3, 66.7	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-7.34 (3.717)	-15.70 (2.628)	-6.75 (10.830)	-31.94 (14.327)	
95% CI [2]	-14.68, 0.00	-20.89, -10.51	-29.97, 16.48	-62.67, -1.22	
Difference (95% CI) in CFB [2]		-8.36 (-16.33, -0.39)		-25.20 (-48.43, -1.97)	
Hedges'G (95% CI) in CFB		-0.30 (-0.64, 0.03)		-0.65 (-1.78, 0.29)	
p-value [3]		0.040		0.036	
					0.314

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-age-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	53.59 (18.090)	51.75 (13.678)	58.66 (16.917)	59.67 (16.366)	
Median	53.24	52.78	58.33	58.33	
Min, Max	23.1, 88.9	26.9, 84.3	22.2, 97.2	13.9, 98.1	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	46.93 (21.465)	41.67 (14.438)	50.10 (15.612)	46.03 (19.089)	
Median	46.76	40.74	52.78	44.91	
Min, Max	15.7, 92.6	6.5, 81.5	16.7, 90.7	6.5, 90.7	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	-5.21 (2.596)	-8.89 (1.747)	-7.69 (1.968)	-13.21 (1.590)	
95% CI [2]	-10.43, 0.02	-12.40, -5.38	-11.58, -3.80	-16.36, -10.07	
Difference (95% CI) in CFB [2]		-3.68 (-9.50, 2.13)		-5.53 (-9.78, -1.27)	
p-value [3]		0.208		0.011	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	93	
Mean (StdDev)	45.48 (23.956)	36.79 (16.006)	49.56 (17.890)	42.22 (19.228)	
Median	46.30	35.19	49.07	38.89	
Min, Max	10.2, 88.0	1.9, 77.8	15.7, 88.0	1.9, 93.5	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-6.79 (3.775)	-13.26 (2.709)	-7.86 (2.285)	-15.89 (1.785)	
95% CI [2]	-14.39, 0.81	-18.71, -7.80	-12.38, -3.34	-19.42, -12.36	
Difference (95% CI) in CFB [2]		-6.47 (-15.01, 2.08)		-8.03 (-12.96, -3.09)	
p-value [3]		0.134		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	47.78 (21.743)	36.52 (16.287)	49.36 (18.546)	42.69 (21.420)	
Median	55.56	35.19	46.30	41.67	
Min, Max	11.1, 80.6	1.9, 79.6	14.8, 87.0	2.8, 90.7	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	-5.13 (3.801)	-13.78 (2.666)	-8.98 (2.647)	-16.98 (2.026)	
95% CI [2]	-12.79, 2.53	-19.16, -8.41	-14.21, -3.74	-20.99, -12.97	
Difference (95% CI) in CFB [2]		-8.65 (-17.15, -0.15)		-8.00 (-13.62, -2.39)	
p-value [3]		0.046		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	88	
Mean (StdDev)	44.99 (24.696)	32.69 (14.752)	48.68 (18.835)	41.46 (21.679)	
Median	49.07	33.33	48.15	37.04	
Min, Max	10.2, 88.0	3.7, 79.6	13.0, 85.2	4.6, 93.5	
C5D1 CFB					
n	16	32	46	86	
LS Mean (StdErr) [2]	-7.85 (4.021)	-17.39 (2.981)	-8.44 (2.755)	-18.21 (2.174)	
95% CI [2]	-15.95, 0.26	-23.39, -11.38	-13.89, -2.99	-22.51, -13.91	
Difference (95% CI) in CFB [2]		-9.54 (-18.58, -0.50)		-9.77 (-15.76, -3.77)	
p-value [3]		0.039		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	49.51 (22.014)	33.04 (16.239)	49.11 (19.477)	40.17 (23.110)	
Median	52.78	31.02	47.22	36.11	
Min, Max	12.0, 89.8	6.5, 86.1	12.0, 87.0	2.8, 92.6	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	-3.49 (4.350)	-18.19 (2.960)	-7.68 (2.839)	-18.84 (2.218)	
95% CI [2]	-12.26, 5.27	-24.16, -12.23	-13.30, -2.07	-23.23, -14.45	
Difference (95% CI) in CFB [2]		-14.70 (-24.46, -4.94)		-11.15 (-17.33, -4.98)	
p-value [3]		0.004		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	48.09 (21.419)	36.18 (16.412)	46.70 (20.979)	38.93 (23.555)	
Median	51.39	33.33	44.44	34.26	
Min, Max	15.7, 87.0	16.7, 89.8	12.0, 89.8	0.9, 92.6	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	-4.39 (4.422)	-14.57 (3.082)	-7.95 (2.985)	-17.74 (2.331)	
95% CI [2]	-13.29, 4.52	-20.78, -8.36	-13.85, -2.04	-22.36, -13.13	
Difference (95% CI) in CFB [2]		-10.18 (-20.09, -0.28)		-9.80 (-16.16, -3.43)	
Hedges'G (95% CI) in CFB		-0.57 (-1.23, 0.04)		-0.46 (-0.84, -0.10)	
p-value [3]		0.044		0.003	
					0.954

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	59.90 (16.386)	61.56 (16.827)	65.17 (17.863)	66.50 (15.647)	
Median	61.11	63.89	65.28	69.44	
Min, Max	30.6, 88.9	22.2, 86.1	13.9, 100.0	16.7, 97.2	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	53.13 (21.846)	50.43 (16.661)	55.99 (17.580)	52.67 (19.101)	
Median	50.00	50.00	55.56	55.56	
Min, Max	25.0, 100.0	11.1, 88.9	11.1, 97.2	8.3, 94.4	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	-6.10 (3.111)	-9.56 (2.093)	-8.21 (2.280)	-13.59 (1.843)	
95% CI [2]	-12.36, 0.15	-13.77, -5.35	-12.72, -3.71	-17.23, -9.95	
Difference (95% CI) in CFB [2]		-3.46 (-10.42, 3.50)		-5.37 (-10.31, -0.44)	
p-value [3]		0.323		0.033	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	94	
Mean (StdDev)	50.49 (22.657)	45.26 (18.470)	55.78 (20.504)	49.31 (20.368)	
Median	50.00	41.67	55.56	50.00	
Min, Max	11.1, 88.9	2.8, 88.9	16.7, 100.0	5.6, 95.8	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-8.24 (3.887)	-13.93 (2.790)	-8.05 (2.657)	-15.73 (2.075)	
95% CI [2]	-16.07, -0.41	-19.55, -8.31	-13.31, -2.80	-19.84, -11.63	
Difference (95% CI) in CFB [2]		-5.69 (-14.49, 3.10)		-7.68 (-13.42, -1.94)	
p-value [3]		0.199		0.009	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	54.26 (21.919)	45.83 (18.892)	55.80 (22.627)	49.82 (21.868)	
Median	55.56	45.83	58.33	50.00	
Min, Max	25.0, 88.9	5.6, 94.4	11.1, 97.2	5.6, 91.7	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	-4.91 (3.868)	-12.73 (2.713)	-9.38 (3.074)	-15.80 (2.354)	
95% CI [2]	-12.70, 2.89	-18.20, -7.27	-15.46, -3.30	-20.46, -11.14	
Difference (95% CI) in CFB [2]		-7.83 (-16.48, 0.82)		-6.42 (-12.94, 0.10)	
p-value [3]		0.075		0.054	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	88	
Mean (StdDev)	51.31 (23.675)	40.82 (16.181)	56.86 (21.483)	49.33 (22.701)	
Median	50.00	40.28	61.11	48.61	
Min, Max	16.7, 91.7	2.8, 75.0	11.1, 94.4	5.6, 100.0	
C5D1 CFB					
n	16	32	46	86	
LS Mean (StdErr) [2]	-7.77 (4.032)	-18.67 (2.989)	-7.74 (3.063)	-16.72 (2.416)	
95% CI [2]	-15.89, 0.36	-24.69, -12.64	-13.80, -1.68	-21.50, -11.93	
Difference (95% CI) in CFB [2]		-10.90 (-19.97, -1.84)		-8.98 (-15.64, -2.31)	
p-value [3]		0.020		0.009	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	55.19 (22.244)	40.86 (17.780)	55.50 (21.103)	46.70 (24.120)	
Median	58.33	38.89	55.56	44.44	
Min, Max	22.2, 94.4	11.1, 88.9	16.7, 97.2	2.8, 97.2	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	-3.71 (4.470)	-19.06 (3.042)	-7.76 (3.165)	-17.59 (2.472)	
95% CI [2]	-12.71, 5.30	-25.19, -12.93	-14.02, -1.50	-22.48, -12.70	
Difference (95% CI) in CFB [2]		-15.35 (-25.38, -5.33)		-9.83 (-16.71, -2.95)	
p-value [3]		0.004		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	52.95 (18.411)	44.96 (16.298)	53.14 (22.010)	46.63 (24.337)	
Median	54.17	40.28	52.78	41.67	
Min, Max	22.2, 80.6	25.0, 94.4	13.9, 97.2	0.0, 100.0	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	-5.52 (4.303)	-14.82 (2.999)	-8.47 (3.341)	-17.04 (2.609)	
95% CI [2]	-14.19, 3.14	-20.86, -8.78	-15.08, -1.85	-22.20, -11.88	
Difference (95% CI) in CFB [2]		-9.30 (-18.94, 0.34)		-8.58 (-15.70, -1.46)	
Hedges'G (95% CI) in CFB		-0.53 (-1.19, 0.08)		-0.36 (-0.73, 0.00)	
p-value [3]		0.058		0.019	
					0.926

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	51.56 (21.324)	49.02 (17.126)	56.49 (23.333)	58.42 (21.837)	
Median	50.00	47.22	55.56	59.72	
Min, Max	16.7, 91.7	19.4, 88.9	13.9, 97.2	5.6, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	43.06 (25.031)	38.75 (17.591)	48.69 (21.781)	44.93 (25.440)	
Median	45.83	33.33	50.00	44.44	
Min, Max	5.6, 91.7	2.8, 86.1	2.8, 91.7	0.0, 100.0	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	-6.36 (3.807)	-9.16 (2.561)	-7.20 (2.446)	-12.84 (1.976)	
95% CI [2]	-14.02, 1.30	-14.31, -4.00	-12.03, -2.36	-16.75, -8.93	
Difference (95% CI) in CFB [2]		-2.80 (-11.32, 5.72)		-5.64 (-10.93, -0.35)	
p-value [3]		0.512		0.037	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	93	
Mean (StdDev)	45.59 (29.398)	34.56 (19.975)	48.28 (21.821)	41.10 (24.497)	
Median	47.22	31.94	44.44	41.67	
Min, Max	5.6, 88.9	2.8, 83.3	5.6, 88.9	0.0, 100.0	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-4.10 (5.232)	-13.18 (3.755)	-7.15 (2.600)	-15.76 (2.031)	
95% CI [2]	-14.63, 6.44	-20.74, -5.61	-12.29, -2.01	-19.77, -11.74	
Difference (95% CI) in CFB [2]		-9.08 (-20.92, 2.76)		-8.61 (-14.22, -2.99)	
p-value [3]		0.129		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	46.48 (24.476)	33.56 (17.269)	46.36 (23.397)	41.79 (26.637)	
Median	58.33	30.56	47.22	41.67	
Min, Max	2.8, 75.0	0.0, 69.4	8.3, 94.4	0.0, 97.2	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	-4.46 (4.906)	-14.86 (3.441)	-9.23 (3.161)	-16.19 (2.420)	
95% CI [2]	-14.34, 5.43	-21.80, -7.93	-15.48, -2.97	-20.98, -11.40	
Difference (95% CI) in CFB [2]		-10.41 (-21.38, 0.56)		-6.96 (-13.67, -0.26)	
p-value [3]		0.062		0.042	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	46	89	
Mean (StdDev)	43.30 (27.622)	30.25 (17.728)	45.53 (23.163)	39.68 (26.545)	
Median	47.22	31.94	44.44	38.89	
Min, Max	0.0, 91.7	2.8, 77.8	0.0, 94.4	0.0, 100.0	
C5D1 CFB					
n	16	32	45	87	
LS Mean (StdErr) [2]	-7.06 (5.379)	-18.28 (3.988)	-8.40 (3.311)	-18.63 (2.587)	
95% CI [2]	-17.90, 3.78	-26.32, -10.25	-14.95, -1.85	-23.75, -13.51	
Difference (95% CI) in CFB [2]		-11.23 (-23.32, 0.87)		-10.23 (-17.44, -3.02)	
p-value [3]		0.068		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	49.44 (25.614)	29.02 (18.836)	47.99 (23.368)	39.32 (27.778)	
Median	50.00	27.78	44.44	36.11	
Min, Max	5.6, 91.7	0.0, 80.6	0.0, 94.4	0.0, 100.0	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	-1.94 (5.568)	-19.58 (3.790)	-6.78 (3.286)	-18.88 (2.567)	
95% CI [2]	-13.16, 9.29	-27.22, -11.94	-13.28, -0.28	-23.96, -13.80	
Difference (95% CI) in CFB [2]		-17.65 (-30.14, -5.15)		-12.11 (-19.25, -4.96)	
p-value [3]		0.007		0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	48.09 (27.698)	33.70 (19.290)	44.75 (25.575)	36.55 (27.966)	
Median	54.17	33.33	45.83	30.56	
Min, Max	2.8, 97.2	5.6, 80.6	0.0, 97.2	0.0, 100.0	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	-2.60 (5.424)	-14.88 (3.781)	-7.04 (3.496)	-18.16 (2.730)	
95% CI [2]	-13.53, 8.32	-22.50, -7.27	-13.96, -0.13	-23.56, -12.76	
Difference (95% CI) in CFB [2]		-12.28 (-24.43, -0.13)		-11.11 (-18.56, -3.66)	
Hedges'G (95% CI) in CFB		-0.56 (-1.22, 0.05)		-0.45 (-0.82, -0.09)	
p-value [3]		0.048		0.004	
					0.867

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	41.67 (22.669)	42.12 (20.026)	51.23 (22.653)	52.30 (24.052)	
Median	43.75	41.67	50.00	54.17	
Min, Max	0.0, 83.3	0.0, 91.7	0.0, 100.0	0.0, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	40.10 (22.663)	33.55 (17.676)	41.75 (22.296)	40.52 (26.486)	
Median	39.58	29.17	41.67	35.42	
Min, Max	0.0, 83.3	0.0, 70.8	0.0, 91.7	0.0, 100.0	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	-0.69 (3.029)	-8.68 (2.038)	-8.74 (2.503)	-12.09 (2.023)	
95% CI [2]	-6.79, 5.40	-12.78, -4.58	-13.69, -3.79	-16.08, -8.09	
Difference (95% CI) in CFB [2]		-7.99 (-14.77, -1.21)		-3.35 (-8.76, 2.07)	
p-value [3]		0.022		0.224	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	94	
Mean (StdDev)	36.03 (25.893)	28.95 (18.372)	41.23 (22.084)	35.46 (23.781)	
Median	33.33	29.17	37.50	33.33	
Min, Max	0.0, 83.3	0.0, 79.2	0.0, 91.7	0.0, 95.8	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-5.51 (4.587)	-12.16 (3.293)	-9.08 (2.607)	-16.85 (2.037)	
95% CI [2]	-14.74, 3.73	-18.79, -5.53	-14.24, -3.92	-20.88, -12.82	
Difference (95% CI) in CFB [2]		-6.66 (-17.04, 3.73)		-7.77 (-13.40, -2.14)	
p-value [3]		0.203		0.007	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	36.94 (24.391)	29.05 (19.732)	42.69 (23.922)	35.73 (25.969)	
Median	33.33	29.17	41.67	33.33	
Min, Max	0.0, 83.3	0.0, 75.0	0.0, 91.7	0.0, 95.8	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	-4.61 (4.411)	-12.79 (3.094)	-9.81 (3.214)	-19.21 (2.460)	
95% CI [2]	-13.50, 4.28	-19.02, -6.55	-16.16, -3.45	-24.08, -14.34	
Difference (95% CI) in CFB [2]		-8.18 (-18.04, 1.69)		-9.40 (-16.22, -2.59)	
p-value [3]		0.102		0.007	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	89	
Mean (StdDev)	35.78 (28.681)	23.84 (17.862)	39.45 (22.670)	33.52 (25.661)	
Median	33.33	22.92	37.50	29.17	
Min, Max	0.0, 95.8	0.0, 87.5	0.0, 87.5	0.0, 91.7	
C5D1 CFB					
n	16	32	46	87	
LS Mean (StdErr) [2]	-7.04 (5.241)	-17.17 (3.885)	-11.25 (3.144)	-20.27 (2.467)	
95% CI [2]	-17.61, 3.52	-25.00, -9.34	-17.47, -5.03	-25.15, -15.39	
Difference (95% CI) in CFB [2]		-10.13 (-21.92, 1.65)		-9.02 (-15.85, -2.19)	
p-value [3]		0.090		0.010	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	38.89 (24.684)	27.19 (20.861)	40.96 (24.959)	32.23 (25.518)	
Median	33.33	22.92	37.50	29.17	
Min, Max	0.0, 79.2	0.0, 91.7	0.0, 100.0	0.0, 95.8	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	-3.61 (4.914)	-17.52 (3.344)	-9.11 (3.366)	-21.26 (2.630)	
95% CI [2]	-13.51, 6.30	-24.26, -10.78	-15.77, -2.45	-26.46, -16.06	
Difference (95% CI) in CFB [2]		-13.92 (-24.94, -2.89)		-12.15 (-19.47, -4.83)	
p-value [3]		0.015		0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	36.20 (25.852)	27.19 (20.658)	38.50 (25.808)	32.12 (27.867)	
Median	31.25	20.83	33.33	25.00	
Min, Max	0.0, 83.3	0.0, 95.8	0.0, 100.0	0.0, 95.8	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	-5.88 (5.436)	-16.01 (3.789)	-8.76 (3.538)	-17.43 (2.763)	
95% CI [2]	-16.83, 5.07	-23.64, -8.38	-15.76, -1.76	-22.90, -11.96	
Difference (95% CI) in CFB [2]		-10.13 (-22.31, 2.05)		-8.67 (-16.21, -1.13)	
Hedges'G (95% CI) in CFB		-0.46 (-1.11, 0.15)		-0.34 (-0.71, 0.02)	
p-value [3]		0.101		0.025	
					0.827

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	64.58 (20.069)	49.77 (22.090)	61.06 (23.554)	57.65 (22.151)	
Median	62.50	50.00	66.67	58.33	
Min, Max	16.7, 91.7	8.3, 100.0	0.0, 100.0	0.0, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	53.65 (23.564)	40.38 (18.881)	53.46 (20.893)	40.48 (18.995)	
Median	45.83	33.33	50.00	41.67	
Min, Max	8.3, 91.7	8.3, 75.0	0.0, 91.7	0.0, 83.3	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	-8.08 (4.213)	-6.50 (2.834)	-5.70 (3.281)	-15.17 (2.652)	
95% CI [2]	-16.56, 0.39	-12.21, -0.80	-12.19, 0.78	-20.42, -9.93	
Difference (95% CI) in CFB [2]		1.58 (-7.85, 11.01)		-9.47 (-16.57, -2.37)	
p-value [3]		0.738		0.009	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	94	
Mean (StdDev)	49.02 (25.665)	33.58 (20.870)	51.33 (21.584)	40.34 (19.296)	
Median	50.00	25.00	50.00	41.67	
Min, Max	8.3, 91.7	0.0, 91.7	0.0, 100.0	0.0, 83.3	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-13.04 (5.894)	-13.82 (4.230)	-7.41 (3.773)	-14.67 (2.947)	
95% CI [2]	-24.91, -1.17	-22.34, -5.30	-14.87, 0.05	-20.50, -8.85	
Difference (95% CI) in CFB [2]		-0.79 (-14.12, 12.55)		-7.26 (-15.41, 0.89)	
p-value [3]		0.906		0.080	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	53.89 (26.515)	32.41 (18.233)	52.41 (22.447)	37.81 (21.016)	
Median	58.33	25.00	50.00	33.33	
Min, Max	16.7, 100.0	0.0, 75.0	0.0, 100.0	0.0, 100.0	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	-8.86 (6.405)	-15.70 (4.493)	-5.80 (4.006)	-18.31 (3.067)	
95% CI [2]	-21.77, 4.05	-24.75, -6.64	-13.73, 2.12	-24.37, -12.24	
Difference (95% CI) in CFB [2]		-6.83 (-21.16, 7.49)		-12.50 (-21.00, -4.00)	
p-value [3]		0.342		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	88	
Mean (StdDev)	49.51 (25.082)	33.33 (16.903)	52.48 (26.970)	37.69 (21.179)	
Median	50.00	33.33	58.33	33.33	
Min, Max	8.3, 100.0	0.0, 83.3	0.0, 100.0	8.3, 100.0	
C5D1 CFB					
n	16	32	46	86	
LS Mean (StdErr) [2]	-12.06 (5.641)	-11.27 (4.182)	-5.17 (3.951)	-18.18 (3.117)	
95% CI [2]	-23.43, -0.69	-19.70, -2.85	-12.99, 2.65	-24.35, -12.01	
Difference (95% CI) in CFB [2]		0.79 (-11.90, 13.47)		-13.01 (-21.61, -4.41)	
p-value [3]		0.901		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	53.89 (21.791)	33.33 (18.884)	49.65 (25.887)	39.01 (23.794)	
Median	58.33	25.00	50.00	33.33	
Min, Max	16.7, 91.7	0.0, 83.3	0.0, 100.0	0.0, 91.7	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	-7.28 (6.584)	-12.76 (4.481)	-7.77 (3.966)	-17.47 (3.098)	
95% CI [2]	-20.55, 5.99	-21.79, -3.73	-15.62, 0.08	-23.60, -11.34	
Difference (95% CI) in CFB [2]		-5.48 (-20.25, 9.29)		-9.70 (-18.32, -1.07)	
p-value [3]		0.459		0.028	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.2a
Change from Baseline in MC-QoL by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	57.29 (21.273)	35.31 (20.360)	49.64 (25.456)	36.61 (21.527)	
Median	58.33	29.17	50.00	33.33	
Min, Max	16.7, 91.7	8.3, 91.7	0.0, 100.0	0.0, 91.7	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	-3.33 (6.581)	-9.98 (4.587)	-7.91 (3.960)	-19.09 (3.092)	
95% CI [2]	-16.59, 9.92	-19.22, -0.74	-15.75, -0.07	-25.21, -12.97	
Difference (95% CI) in CFB [2]		-6.65 (-21.39, 8.10)		-11.18 (-19.62, -2.74)	
Hedges'G (95% CI) in CFB		-0.25 (-0.89, 0.37)		-0.40 (-0.77, -0.04)	
p-value [3]		0.369		0.010	
					0.558

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-sex-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	54.74 (19.504)	56.60 (16.349)	59.62 (15.058)	58.11 (15.867)	
Median	51.39	56.48	62.50	57.87	
Min, Max	22.2, 97.2	26.9, 87.0	23.1, 83.3	13.9, 98.1	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	47.55 (18.685)	42.96 (17.294)	50.85 (15.639)	46.17 (18.413)	
Median	42.59	41.67	52.78	46.30	
Min, Max	19.4, 92.6	15.7, 88.9	15.7, 82.4	6.5, 90.7	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	-6.47 (2.681)	-14.13 (2.097)	-7.41 (1.970)	-10.36 (1.492)	
95% CI [2]	-11.81, -1.13	-18.31, -9.95	-11.31, -3.51	-13.32, -7.41	
Difference (95% CI) in CFB [2]		-7.66 (-13.51, -1.81)		-2.95 (-7.29, 1.38)	
p-value [3]		0.011		0.180	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	51	37	76	
Mean (StdDev)	46.61 (20.079)	41.09 (18.409)	50.08 (19.138)	40.56 (18.708)	
Median	46.76	37.96	52.78	37.96	
Min, Max	10.2, 88.0	10.2, 88.0	14.8, 86.1	1.9, 93.5	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	-6.74 (3.093)	-14.06 (2.443)	-8.21 (2.441)	-16.23 (1.809)	
95% CI [2]	-12.90, -0.57	-18.93, -9.19	-13.04, -3.37	-19.82, -12.65	
Difference (95% CI) in CFB [2]		-7.32 (-14.11, -0.53)		-8.03 (-13.41, -2.64)	
p-value [3]		0.035		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	46.82 (20.783)	38.48 (17.755)	50.30 (18.338)	42.64 (21.723)	
Median	43.52	35.19	55.56	41.67	
Min, Max	14.8, 80.6	9.3, 86.1	11.1, 87.0	1.9, 90.7	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	-9.58 (3.674)	-18.79 (2.737)	-7.75 (2.634)	-15.19 (1.968)	
95% CI [2]	-16.92, -2.24	-24.26, -13.33	-12.97, -2.53	-19.09, -11.29	
Difference (95% CI) in CFB [2]		-9.21 (-16.80, -1.62)		-7.44 (-13.26, -1.63)	
p-value [3]		0.018		0.013	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	46	37	78	
Mean (StdDev)	43.28 (21.891)	37.82 (18.952)	50.93 (18.911)	39.55 (21.081)	
Median	42.59	33.33	51.85	35.65	
Min, Max	10.2, 85.2	11.1, 93.5	11.1, 88.0	3.7, 86.1	
C5D1 CFB					
n	25	41	37	77	
LS Mean (StdErr) [2]	-11.50 (3.620)	-19.13 (2.992)	-6.76 (2.893)	-17.63 (2.150)	
95% CI [2]	-18.74, -4.26	-25.12, -13.15	-12.49, -1.03	-21.89, -13.37	
Difference (95% CI) in CFB [2]		-7.64 (-15.60, 0.32)		-10.87 (-17.25, -4.50)	
p-value [3]		0.060		0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	46.93 (21.380)	33.48 (19.198)	50.75 (19.038)	41.17 (22.522)	
Median	44.44	28.70	51.85	38.89	
Min, Max	12.0, 89.8	7.4, 92.6	12.0, 83.3	2.8, 92.6	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	-7.61 (3.756)	-23.85 (2.877)	-6.72 (2.930)	-15.78 (2.171)	
95% CI [2]	-15.12, -0.11	-29.60, -18.10	-12.53, -0.92	-20.08, -11.47	
Difference (95% CI) in CFB [2]		-16.24 (-24.43, -8.04)		-9.06 (-15.52, -2.59)	
p-value [3]		<0.001		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	42.07 (21.305)	34.06 (19.944)	50.43 (20.260)	40.74 (22.404)	
Median	42.59	27.31	52.78	37.96	
Min, Max	12.0, 85.2	8.3, 91.7	13.9, 89.8	0.9, 92.6	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-9.27 (4.009)	-21.12 (3.136)	-6.16 (3.128)	-14.73 (2.319)	
95% CI [2]	-17.29, -1.26	-27.39, -14.85	-12.36, 0.05	-19.33, -10.13	
Difference (95% CI) in CFB [2]		-11.85 (-20.17, -3.52)		-8.57 (-15.48, -1.67)	
Hedges'G (95% CI) in CFB		-0.57 (-1.11, -0.07)		-0.43 (-0.84, -0.04)	
p-value [3]		0.006		0.015	
					0.555

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	59.81 (20.173)	64.65 (16.533)	67.18 (14.640)	65.49 (15.836)	
Median	56.94	66.67	66.67	66.67	
Min, Max	13.9, 100.0	25.0, 94.4	33.3, 97.2	16.7, 97.2	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	52.63 (20.253)	50.76 (17.630)	57.53 (16.939)	52.99 (19.029)	
Median	52.78	50.00	56.94	55.56	
Min, Max	11.1, 100.0	11.1, 94.4	25.0, 97.2	8.3, 91.7	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	-6.67 (3.205)	-14.05 (2.507)	-8.44 (2.218)	-11.29 (1.680)	
95% CI [2]	-13.05, -0.29	-19.05, -9.06	-12.83, -4.04	-14.62, -7.96	
Difference (95% CI) in CFB [2]		-7.38 (-14.38, -0.39)		-2.85 (-7.73, 2.03)	
p-value [3]		0.039		0.250	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	52	37	76	
Mean (StdDev)	51.85 (22.594)	49.33 (19.941)	56.53 (19.720)	47.48 (19.955)	
Median	54.17	47.22	55.56	44.44	
Min, Max	11.1, 100.0	5.6, 95.8	19.4, 97.2	2.8, 91.7	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	-7.43 (3.539)	-15.03 (2.795)	-8.93 (2.781)	-15.97 (2.061)	
95% CI [2]	-14.49, -0.38	-20.60, -9.45	-14.44, -3.42	-20.06, -11.89	
Difference (95% CI) in CFB [2]		-7.59 (-15.36, 0.17)		-7.04 (-13.18, -0.91)	
p-value [3]		0.055		0.025	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	53.62 (25.382)	46.53 (18.466)	56.53 (20.404)	50.18 (22.680)	
Median	47.22	44.44	61.11	52.78	
Min, Max	11.1, 94.4	8.3, 91.7	25.0, 97.2	5.6, 94.4	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	-9.01 (4.441)	-18.18 (3.307)	-8.59 (2.902)	-13.98 (2.168)	
95% CI [2]	-17.89, -0.14	-24.78, -11.57	-14.34, -2.84	-18.28, -9.69	
Difference (95% CI) in CFB [2]		-9.16 (-18.34, 0.01)		-5.39 (-11.80, 1.02)	
p-value [3]		0.050		0.098	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	46	37	78	
Mean (StdDev)	51.23 (24.741)	46.38 (20.081)	58.42 (19.623)	47.14 (22.123)	
Median	50.00	41.67	61.11	50.00	
Min, Max	11.1, 91.7	16.7, 100.0	19.4, 94.4	2.8, 90.6	
C5D1 CFB					
n	25	41	37	77	
LS Mean (StdErr) [2]	-9.92 (3.908)	-17.90 (3.231)	-7.03 (3.176)	-17.21 (2.361)	
95% CI [2]	-17.74, -2.11	-24.36, -11.44	-13.33, -0.74	-21.89, -12.54	
Difference (95% CI) in CFB [2]		-7.97 (-16.57, 0.62)		-10.18 (-17.18, -3.19)	
p-value [3]		0.068		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	52.44 (23.203)	40.87 (19.263)	57.43 (19.805)	47.76 (24.216)	
Median	47.22	40.28	58.33	47.22	
Min, Max	16.7, 94.4	2.8, 97.2	22.2, 97.2	2.8, 94.4	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	-7.86 (4.150)	-23.38 (3.179)	-6.94 (3.208)	-15.20 (2.378)	
95% CI [2]	-16.15, 0.42	-29.72, -17.03	-13.30, -0.58	-19.91, -10.48	
Difference (95% CI) in CFB [2]		-15.51 (-24.57, -6.45)		-8.25 (-15.33, -1.17)	
p-value [3]		0.001		0.023	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	47.11 (21.791)	42.22 (21.125)	57.13 (19.713)	48.67 (22.623)	
Median	52.78	37.50	55.56	47.22	
Min, Max	13.9, 83.3	13.9, 100.0	16.7, 97.2	0.0, 94.4	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-8.56 (4.601)	-20.90 (3.599)	-7.59 (3.276)	-14.11 (2.428)	
95% CI [2]	-17.76, 0.63	-28.10, -13.71	-14.08, -1.10	-18.92, -9.30	
Difference (95% CI) in CFB [2]		-12.34 (-21.90, -2.78)		-6.52 (-13.75, 0.71)	
Hedges'G (95% CI) in CFB		-0.52 (-1.06, -0.02)		-0.31 (-0.72, 0.08)	
p-value [3]		0.012		0.077	
					0.344

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	49.94 (23.817)	51.16 (21.227)	59.58 (21.358)	59.06 (20.382)	
Median	47.22	52.78	61.11	59.72	
Min, Max	13.9, 97.2	16.7, 94.4	13.9, 94.4	5.6, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	42.38 (24.205)	38.37 (22.081)	51.46 (20.451)	46.79 (24.158)	
Median	33.33	33.33	55.56	48.61	
Min, Max	5.6, 91.7	0.0, 100.0	2.8, 88.9	2.8, 100.0	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	-7.26 (3.391)	-13.53 (2.652)	-6.50 (2.564)	-10.34 (1.943)	
95% CI [2]	-14.01, -0.51	-18.81, -8.25	-11.58, -1.42	-14.19, -6.49	
Difference (95% CI) in CFB [2]		-6.27 (-13.67, 1.13)		-3.84 (-9.49, 1.80)	
p-value [3]		0.096		0.180	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	51	37	76	
Mean (StdDev)	44.07 (23.792)	36.93 (22.569)	50.45 (23.666)	40.97 (24.076)	
Median	37.50	33.33	55.56	41.67	
Min, Max	5.6, 88.9	2.8, 94.4	5.6, 88.9	0.0, 100.0	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	-4.38 (3.635)	-12.31 (2.871)	-7.64 (2.985)	-17.07 (2.212)	
95% CI [2]	-11.62, 2.87	-18.03, -6.58	-13.56, -1.72	-21.46, -12.69	
Difference (95% CI) in CFB [2]		-7.93 (-15.91, 0.05)		-9.43 (-16.02, -2.84)	
p-value [3]		0.051		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	42.27 (25.568)	33.76 (21.364)	48.95 (22.022)	43.36 (25.988)	
Median	36.11	30.56	50.00	44.44	
Min, Max	8.3, 88.9	0.0, 94.4	2.8, 94.4	0.0, 97.2	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	-7.96 (4.696)	-17.72 (3.498)	-8.27 (3.158)	-14.84 (2.359)	
95% CI [2]	-17.34, 1.42	-24.71, -10.74	-14.53, -2.01	-19.52, -10.17	
Difference (95% CI) in CFB [2]		-9.76 (-19.47, -0.06)		-6.57 (-13.55, 0.40)	
p-value [3]		0.049		0.064	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	36	78	
Mean (StdDev)	37.76 (25.110)	33.57 (22.259)	50.31 (22.418)	39.01 (25.894)	
Median	38.89	30.56	48.61	38.89	
Min, Max	0.0, 83.3	2.8, 100.0	8.3, 94.4	0.0, 100.0	
C5D1 CFB					
n	25	42	36	77	
LS Mean (StdErr) [2]	-10.59 (4.471)	-18.40 (3.657)	-6.55 (3.598)	-18.72 (2.657)	
95% CI [2]	-19.53, -1.65	-25.71, -11.09	-13.68, 0.58	-23.99, -13.45	
Difference (95% CI) in CFB [2]		-7.81 (-17.58, 1.97)		-12.17 (-20.11, -4.23)	
p-value [3]		0.116		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	44.33 (24.800)	28.42 (22.308)	51.05 (22.909)	41.59 (26.814)	
Median	41.67	25.00	52.78	44.44	
Min, Max	0.0, 91.7	0.0, 100.0	5.6, 94.4	0.0, 100.0	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	-5.72 (4.434)	-23.85 (3.396)	-6.16 (3.520)	-16.37 (2.609)	
95% CI [2]	-14.57, 3.14	-30.63, -17.07	-13.14, 0.82	-21.54, -11.20	
Difference (95% CI) in CFB [2]		-18.13 (-27.81, -8.46)		-10.21 (-17.97, -2.44)	
p-value [3]		<0.001		0.010	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	39.00 (25.691)	28.89 (23.227)	50.08 (25.496)	40.12 (26.296)	
Median	36.11	23.61	52.78	38.89	
Min, Max	2.8, 91.7	0.0, 100.0	0.0, 97.2	0.0, 100.0	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-7.11 (4.622)	-20.41 (3.615)	-5.61 (3.798)	-15.67 (2.815)	
95% CI [2]	-16.34, 2.13	-27.63, -13.18	-13.14, 1.92	-21.25, -10.09	
Difference (95% CI) in CFB [2]		-13.30 (-22.90, -3.70)		-10.07 (-18.45, -1.68)	
Hedges'G (95% CI) in CFB		-0.56 (-1.10, -0.06)		-0.42 (-0.82, -0.02)	
p-value [3]		0.007		0.019	
					0.620

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	50.06 (25.743)	53.18 (22.793)	48.14 (20.611)	46.98 (23.607)	
Median	47.92	50.00	47.92	45.83	
Min, Max	0.0, 100.0	8.3, 100.0	0.0, 87.5	0.0, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	43.68 (24.245)	40.40 (23.292)	39.47 (20.567)	37.13 (25.342)	
Median	41.67	33.33	41.67	33.33	
Min, Max	0.0, 91.7	4.2, 100.0	0.0, 75.0	0.0, 100.0	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	-5.09 (3.144)	-14.30 (2.460)	-7.96 (2.623)	-8.69 (1.987)	
95% CI [2]	-11.35, 1.17	-19.20, -9.40	-13.15, -2.76	-12.63, -4.75	
Difference (95% CI) in CFB [2]		-9.21 (-16.07, -2.35)		-0.74 (-6.51, 5.04)	
p-value [3]		0.009		0.801	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	52	37	76	
Mean (StdDev)	39.56 (22.416)	38.70 (22.527)	40.20 (23.799)	30.33 (22.136)	
Median	37.50	37.50	37.50	27.08	
Min, Max	0.0, 83.3	0.0, 95.8	0.0, 91.7	0.0, 95.8	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	-8.66 (3.800)	-14.73 (3.002)	-7.43 (2.735)	-16.12 (2.027)	
95% CI [2]	-16.24, -1.09	-20.71, -8.74	-12.85, -2.00	-20.14, -12.10	
Difference (95% CI) in CFB [2]		-6.06 (-14.40, 2.28)		-8.69 (-14.73, -2.66)	
p-value [3]		0.152		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	38.59 (22.446)	35.42 (22.635)	42.91 (25.017)	32.82 (25.776)	
Median	37.50	33.33	45.83	25.00	
Min, Max	0.0, 83.3	0.0, 95.8	0.0, 91.7	0.0, 95.8	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	-14.55 (4.300)	-20.19 (3.203)	-5.98 (3.227)	-16.66 (2.410)	
95% CI [2]	-23.14, -5.96	-26.59, -13.79	-12.37, 0.42	-21.44, -11.88	
Difference (95% CI) in CFB [2]		-5.64 (-14.53, 3.24)		-10.68 (-17.80, -3.56)	
p-value [3]		0.209		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	37	78	
Mean (StdDev)	35.03 (24.330)	31.91 (22.958)	40.99 (24.167)	30.02 (24.749)	
Median	37.50	25.00	45.83	25.00	
Min, Max	0.0, 87.5	0.0, 91.7	0.0, 95.8	0.0, 91.7	
C5D1 CFB					
n	25	42	37	77	
LS Mean (StdErr) [2]	-16.76 (4.304)	-23.40 (3.521)	-6.54 (3.376)	-17.76 (2.509)	
95% CI [2]	-25.36, -8.16	-30.44, -16.36	-13.23, 0.15	-22.73, -12.79	
Difference (95% CI) in CFB [2]		-6.64 (-16.05, 2.77)		-11.21 (-18.65, -3.78)	
p-value [3]		0.163		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	39.67 (24.030)	29.41 (23.634)	40.99 (25.468)	31.66 (24.801)	
Median	37.50	20.83	37.50	33.33	
Min, Max	0.0, 91.7	0.0, 83.3	0.0, 100.0	0.0, 95.8	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	-10.72 (4.529)	-26.69 (3.469)	-6.54 (3.451)	-16.56 (2.558)	
95% CI [2]	-19.77, -1.68	-33.62, -19.76	-13.38, 0.30	-21.63, -11.49	
Difference (95% CI) in CFB [2]		-15.97 (-25.85, -6.09)		-10.01 (-17.63, -2.40)	
p-value [3]		0.002		0.010	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	34.67 (23.221)	30.42 (24.474)	40.09 (27.223)	30.79 (27.004)	
Median	29.17	22.92	33.33	25.00	
Min, Max	0.0, 87.5	0.0, 91.7	0.0, 100.0	0.0, 95.8	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-12.71 (4.511)	-21.49 (3.528)	-6.04 (3.829)	-15.16 (2.838)	
95% CI [2]	-21.73, -3.70	-28.54, -14.44	-13.63, 1.55	-20.78, -9.53	
Difference (95% CI) in CFB [2]		-8.78 (-18.15, 0.60)		-9.11 (-17.56, -0.66)	
Hedges'G (95% CI) in CFB		-0.38 (-0.91, 0.13)		-0.37 (-0.78, 0.02)	
p-value [3]		0.066		0.035	
					0.945

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	64.17 (23.279)	55.61 (23.573)	60.09 (22.357)	55.42 (21.589)	
Median	70.83	58.33	62.50	58.33	
Min, Max	16.7, 100.0	8.3, 100.0	0.0, 91.7	0.0, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	55.65 (20.681)	38.56 (19.811)	51.75 (22.019)	41.88 (18.167)	
Median	58.33	33.33	50.00	41.67	
Min, Max	16.7, 91.7	0.0, 83.3	0.0, 91.7	0.0, 83.3	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	-6.74 (4.607)	-15.39 (3.604)	-5.96 (3.252)	-10.99 (2.464)	
95% CI [2]	-15.92, 2.43	-22.57, -8.21	-12.40, 0.49	-15.87, -6.11	
Difference (95% CI) in CFB [2]		-8.65 (-18.70, 1.41)		-5.03 (-12.19, 2.13)	
p-value [3]		0.091		0.166	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	52	37	76	
Mean (StdDev)	52.50 (20.430)	37.98 (19.485)	49.32 (24.246)	38.93 (20.248)	
Median	58.33	33.33	50.00	41.67	
Min, Max	16.7, 91.7	0.0, 91.7	0.0, 100.0	0.0, 83.3	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	-8.72 (5.031)	-14.87 (3.975)	-9.25 (4.047)	-14.78 (2.999)	
95% CI [2]	-18.75, 1.32	-22.80, -6.95	-17.27, -1.23	-20.72, -8.83	
Difference (95% CI) in CFB [2]		-6.16 (-17.20, 4.89)		-5.53 (-14.46, 3.40)	
p-value [3]		0.270		0.222	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	56.52 (22.467)	34.62 (19.761)	50.45 (23.810)	37.45 (20.795)	
Median	58.33	33.33	50.00	33.33	
Min, Max	16.7, 100.0	0.0, 100.0	0.0, 100.0	0.0, 91.7	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	-7.32 (5.636)	-20.83 (4.198)	-7.14 (4.158)	-16.96 (3.106)	
95% CI [2]	-18.58, 3.95	-29.22, -12.45	-15.38, 1.10	-23.12, -10.81	
Difference (95% CI) in CFB [2]		-13.52 (-25.17, -1.87)		-9.82 (-19.00, -0.64)	
p-value [3]		0.024		0.036	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	46	37	78	
Mean (StdDev)	52.47 (28.478)	34.60 (19.951)	51.13 (25.013)	37.50 (20.179)	
Median	50.00	33.33	58.33	33.33	
Min, Max	8.3, 100.0	0.0, 100.0	0.0, 91.7	8.3, 91.7	
C5D1 CFB					
n	25	41	37	77	
LS Mean (StdErr) [2]	-9.37 (5.176)	-18.63 (4.279)	-6.19 (4.260)	-15.55 (3.166)	
95% CI [2]	-19.72, 0.98	-27.19, -10.07	-14.63, 2.25	-21.82, -9.28	
Difference (95% CI) in CFB [2]		-9.26 (-20.65, 2.12)		-9.36 (-18.74, 0.03)	
p-value [3]		0.109		0.051	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	52.67 (27.504)	34.62 (20.637)	49.32 (23.189)	39.18 (23.689)	
Median	58.33	33.33	50.00	33.33	
Min, Max	0.0, 100.0	0.0, 91.7	0.0, 100.0	0.0, 91.7	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	-7.26 (5.461)	-19.37 (4.183)	-8.10 (4.258)	-14.19 (3.156)	
95% CI [2]	-18.17, 3.64	-27.72, -11.01	-16.54, 0.34	-20.45, -7.94	
Difference (95% CI) in CFB [2]		-12.10 (-24.02, -0.19)		-6.09 (-15.49, 3.31)	
p-value [3]		0.047		0.202	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.3a
Change from Baseline in MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	51.00 (28.395)	32.33 (17.789)	52.03 (21.908)	38.74 (22.772)	
Median	50.00	25.00	50.00	33.33	
Min, Max	0.0, 100.0	8.3, 83.3	0.0, 91.7	0.0, 91.7	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-11.95 (5.844)	-22.96 (4.571)	-3.71 (4.138)	-12.90 (3.067)	
95% CI [2]	-23.62, -0.27	-32.09, -13.82	-11.91, 4.49	-18.98, -6.82	
Difference (95% CI) in CFB [2]		-11.01 (-23.15, 1.13)		-9.19 (-18.32, -0.05)	
Hedges'G (95% CI) in CFB		-0.37 (-0.89, 0.14)		-0.35 (-0.75, 0.05)	
p-value [3]		0.075		0.049	
					0.764

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-reg-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.4a
Change from Baseline in MC-QoL by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-cou-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.4a
Change from Baseline in MC-QoL by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-cou-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.4a
Change from Baseline in MC-QoL by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-cou-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.4a
Change from Baseline in MC-QoL by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-cou-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.4a
Change from Baseline in MC-QoL by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-cou-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.4a
Change from Baseline in MC-QoL by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-cou-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.4a
Change from Baseline in MC-QoL by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-cou-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.4a
Change from Baseline in MC-QoL by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-cou-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.4a
Change from Baseline in MC-QoL by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-cou-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.4a
Change from Baseline in MC-QoL by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-cou-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.4a
Change from Baseline in MC-QoL by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-cou-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.4a
Change from Baseline in MC-QoL by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-cou-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.4a
Change from Baseline in MC-QoL by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-cou-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.4a
Change from Baseline in MC-QoL by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-cou-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.4a
Change from Baseline in MC-QoL by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-cou-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.4a
Change from Baseline in MC-QoL by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-cou-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.4a
Change from Baseline in MC-QoL by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-cou-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.4a
Change from Baseline in MC-QoL by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-cou-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.4a
Change from Baseline in MC-QoL by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-cou-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.4a
Change from Baseline in MC-QoL by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-cou-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.4a
Change from Baseline in MC-QoL by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-cou-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.4a
Change from Baseline in MC-QoL by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-cou-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.4a
Change from Baseline in MC-QoL by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-cou-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.4a
Change from Baseline in MC-QoL by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-cou-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.4a
Change from Baseline in MC-QoL by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-cou-a.sas Date: 15:51/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	48.23 (15.673)	47.22 (12.769)	62.51 (15.995)	63.45 (14.790)	
Median	47.69	50.93	62.96	64.81	
Min, Max	22.2, 78.7	13.9, 75.9	35.2, 97.2	32.4, 98.1	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	42.00 (15.997)	36.38 (14.157)	53.56 (16.310)	49.60 (18.368)	
Median	40.74	34.72	53.70	49.07	
Min, Max	15.7, 79.6	6.5, 68.5	24.0, 92.6	14.8, 90.7	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	-4.73 (2.477)	-9.95 (1.690)	-8.83 (2.035)	-13.67 (1.641)	
95% CI [2]	-9.67, 0.21	-13.32, -6.58	-12.86, -4.80	-16.92, -10.42	
Difference (95% CI) in CFB [2]		-5.22 (-10.42, -0.03)		-4.84 (-9.54, -0.15)	
p-value [3]		0.049		0.043	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	77	
Mean (StdDev)	41.62 (15.553)	32.87 (14.685)	51.90 (20.470)	45.53 (19.194)	
Median	44.44	32.87	50.00	46.30	
Min, Max	14.8, 71.3	1.9, 69.4	10.2, 88.0	1.9, 93.5	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	-4.28 (3.173)	-12.67 (2.080)	-10.26 (2.356)	-17.70 (1.944)	
95% CI [2]	-10.62, 2.06	-16.83, -8.52	-14.92, -5.59	-21.55, -13.85	
Difference (95% CI) in CFB [2]		-8.39 (-15.08, -1.71)		-7.45 (-12.95, -1.95)	
p-value [3]		0.015		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	40.96 (18.994)	32.21 (16.188)	53.28 (18.133)	45.97 (20.937)	
Median	37.96	31.48	55.56	46.30	
Min, Max	11.1, 73.1	1.9, 77.8	16.7, 87.0	2.8, 90.7	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	-4.87 (3.294)	-14.24 (2.243)	-10.09 (2.751)	-17.79 (2.110)	
95% CI [2]	-11.45, 1.72	-18.73, -9.76	-15.54, -4.65	-21.97, -13.61	
Difference (95% CI) in CFB [2]		-9.38 (-16.26, -2.49)		-7.70 (-13.91, -1.49)	
p-value [3]		0.008		0.016	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	44	41	78	
Mean (StdDev)	39.37 (19.556)	30.74 (14.176)	52.37 (19.585)	43.87 (21.682)	
Median	38.89	29.63	52.78	42.13	
Min, Max	10.2, 75.9	3.7, 71.3	11.1, 88.0	4.6, 93.5	
C5D1 CFB					
n	21	41	41	76	
LS Mean (StdErr) [2]	-5.18 (3.595)	-15.60 (2.550)	-10.74 (2.821)	-20.30 (2.233)	
95% CI [2]	-12.37, 2.01	-20.71, -10.50	-16.33, -5.15	-24.73, -15.88	
Difference (95% CI) in CFB [2]		-10.42 (-18.02, -2.83)		-9.56 (-16.08, -3.04)	
p-value [3]		0.008		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	43.20 (17.474)	29.82 (14.604)	52.75 (20.646)	43.34 (23.386)	
Median	43.52	29.63	51.85	46.30	
Min, Max	12.0, 74.1	5.6, 77.8	12.0, 89.8	2.8, 92.6	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	-2.44 (3.158)	-16.84 (2.160)	-9.86 (3.134)	-20.58 (2.433)	
95% CI [2]	-8.75, 3.87	-21.15, -12.52	-16.07, -3.65	-25.40, -15.76	
Difference (95% CI) in CFB [2]		-14.40 (-21.03, -7.76)		-10.72 (-17.95, -3.50)	
p-value [3]		<0.0001		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	39.94 (18.736)	32.14 (16.101)	50.97 (21.250)	42.06 (23.875)	
Median	41.67	29.63	51.39	40.74	
Min, Max	13.0, 68.5	4.6, 82.4	12.0, 89.8	0.9, 92.6	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	-3.82 (3.427)	-13.07 (2.363)	-9.74 (3.202)	-19.98 (2.529)	
95% CI [2]	-10.67, 3.03	-17.79, -8.35	-16.09, -3.40	-24.99, -14.97	
Difference (95% CI) in CFB [2]		-9.25 (-16.38, -2.12)		-10.24 (-17.54, -2.94)	
Hedges'G (95% CI) in CFB		-0.58 (-1.15, -0.06)		-0.48 (-0.88, -0.09)	
p-value [3]		0.012		0.006	
					0.835

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	53.94 (17.297)	55.27 (15.929)	69.38 (15.291)	70.88 (13.285)	
Median	55.56	58.33	70.83	72.22	
Min, Max	13.9, 91.7	16.7, 86.1	36.1, 100.0	36.1, 97.2	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	49.22 (18.435)	42.90 (15.461)	58.80 (17.858)	57.25 (18.185)	
Median	47.22	41.67	59.72	55.56	
Min, Max	11.1, 97.2	8.3, 77.8	22.2, 100.0	11.1, 94.4	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	-2.47 (2.934)	-10.72 (2.002)	-10.80 (2.331)	-13.95 (1.880)	
95% CI [2]	-8.32, 3.39	-14.71, -6.72	-15.41, -6.18	-17.67, -10.22	
Difference (95% CI) in CFB [2]		-8.25 (-14.40, -2.10)		-3.15 (-8.53, 2.23)	
p-value [3]		0.009		0.249	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	78	
Mean (StdDev)	47.98 (18.188)	39.35 (16.372)	57.59 (21.771)	53.51 (20.235)	
Median	43.06	41.67	58.33	52.78	
Min, Max	22.2, 97.2	2.8, 83.3	11.1, 100.0	5.6, 95.8	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	-3.52 (3.650)	-13.86 (2.392)	-11.23 (2.646)	-17.06 (2.183)	
95% CI [2]	-10.81, 3.78	-18.64, -9.08	-16.47, -5.99	-21.38, -12.74	
Difference (95% CI) in CFB [2]		-10.35 (-18.04, -2.65)		-5.83 (-12.00, 0.35)	
p-value [3]		0.009		0.064	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	46.69 (22.389)	40.28 (17.121)	60.11 (21.025)	53.57 (21.939)	
Median	41.67	40.28	63.89	55.56	
Min, Max	11.1, 94.4	5.6, 77.8	11.1, 97.2	8.3, 94.4	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	-4.27 (3.708)	-13.32 (2.525)	-11.13 (3.134)	-16.87 (2.404)	
95% CI [2]	-11.69, 3.14	-18.37, -8.27	-17.33, -4.92	-21.64, -12.11	
Difference (95% CI) in CFB [2]		-9.05 (-16.80, -1.30)		-5.75 (-12.83, 1.33)	
p-value [3]		0.023		0.110	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	44	41	78	
Mean (StdDev)	46.38 (21.146)	38.01 (16.161)	60.44 (21.113)	52.23 (22.298)	
Median	47.22	36.11	63.89	52.78	
Min, Max	11.1, 88.9	2.8, 72.2	13.9, 94.4	8.3, 100.0	
C5D1 CFB					
n	21	41	41	76	
LS Mean (StdErr) [2]	-4.93 (4.249)	-15.20 (3.014)	-9.94 (2.982)	-19.33 (2.360)	
95% CI [2]	-13.43, 3.57	-21.23, -9.17	-15.85, -4.04	-24.00, -14.65	
Difference (95% CI) in CFB [2]		-10.27 (-19.25, -1.29)		-9.38 (-16.27, -2.49)	
p-value [3]		0.026		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	49.88 (18.923)	37.38 (17.085)	58.69 (22.013)	50.04 (24.103)	
Median	47.22	33.33	61.11	50.00	
Min, Max	16.7, 88.9	8.3, 83.3	19.4, 97.2	2.8, 97.2	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	-0.84 (3.898)	-16.23 (2.666)	-11.11 (3.319)	-20.16 (2.577)	
95% CI [2]	-8.63, 6.95	-21.56, -10.91	-17.68, -4.53	-25.27, -15.06	
Difference (95% CI) in CFB [2]		-15.39 (-23.58, -7.21)		-9.05 (-16.71, -1.40)	
p-value [3]		<0.001		0.021	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	46.46 (18.921)	40.05 (16.987)	56.74 (21.405)	50.14 (24.329)	
Median	47.22	38.89	55.56	50.00	
Min, Max	13.9, 88.9	11.1, 83.3	13.9, 97.2	0.0, 100.0	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	-2.71 (4.183)	-12.02 (2.884)	-11.26 (3.342)	-19.92 (2.639)	
95% CI [2]	-11.08, 5.65	-17.78, -6.25	-17.89, -4.64	-25.15, -14.69	
Difference (95% CI) in CFB [2]		-9.30 (-18.00, -0.60)		-8.65 (-16.27, -1.04)	
Hedges'G (95% CI) in CFB		-0.48 (-1.04, 0.05)		-0.39 (-0.78, -0.00)	
p-value [3]		0.036		0.026	
					0.963

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	48.61 (23.937)	46.54 (17.435)	58.99 (21.584)	61.21 (21.244)	
Median	48.61	47.22	61.11	63.89	
Min, Max	13.9, 94.4	5.6, 80.6	16.7, 97.2	5.6, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	39.89 (22.608)	35.17 (19.909)	51.64 (21.561)	47.84 (24.654)	
Median	33.33	33.33	55.56	44.44	
Min, Max	2.8, 86.1	2.8, 77.8	5.6, 91.7	0.0, 100.0	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	-5.90 (3.339)	-9.82 (2.278)	-7.27 (2.533)	-12.96 (2.043)	
95% CI [2]	-12.56, 0.76	-14.37, -5.28	-12.28, -2.26	-17.00, -8.91	
Difference (95% CI) in CFB [2]		-3.92 (-10.92, 3.08)		-5.69 (-11.53, 0.16)	
p-value [3]		0.268		0.056	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	77	
Mean (StdDev)	42.17 (20.585)	31.31 (18.610)	50.25 (24.950)	44.23 (25.113)	
Median	40.28	30.56	47.22	44.44	
Min, Max	5.6, 75.0	2.8, 80.6	5.6, 88.9	0.0, 100.0	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	-3.02 (4.121)	-12.61 (2.701)	-8.37 (2.732)	-17.16 (2.254)	
95% CI [2]	-11.26, 5.21	-18.01, -7.22	-13.78, -2.96	-21.62, -12.69	
Difference (95% CI) in CFB [2]		-9.59 (-18.28, -0.91)		-8.79 (-15.17, -2.41)	
p-value [3]		0.031		0.007	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	38.49 (24.221)	30.86 (20.590)	50.64 (22.199)	44.38 (25.700)	
Median	36.11	27.78	50.00	44.44	
Min, Max	2.8, 80.6	0.0, 86.1	13.9, 94.4	0.0, 97.2	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	-5.73 (4.539)	-13.00 (3.091)	-8.71 (3.147)	-17.26 (2.414)	
95% CI [2]	-14.81, 3.35	-19.18, -6.82	-14.95, -2.48	-22.04, -12.48	
Difference (95% CI) in CFB [2]		-7.27 (-16.76, 2.21)		-8.54 (-15.65, -1.44)	
p-value [3]		0.130		0.019	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	40	78	
Mean (StdDev)	37.44 (24.214)	29.63 (17.796)	49.24 (23.469)	41.58 (27.036)	
Median	38.89	27.78	48.61	41.67	
Min, Max	0.0, 83.3	0.0, 80.6	0.0, 94.4	0.0, 100.0	
C5D1 CFB					
n	21	42	40	76	
LS Mean (StdErr) [2]	-5.24 (4.824)	-15.59 (3.410)	-9.57 (3.356)	-20.60 (2.634)	
95% CI [2]	-14.89, 4.41	-22.41, -8.77	-16.22, -2.92	-25.82, -15.38	
Difference (95% CI) in CFB [2]		-10.35 (-20.49, -0.20)		-11.03 (-18.78, -3.28)	
p-value [3]		0.046		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	40.82 (21.751)	28.07 (18.763)	52.78 (23.980)	41.53 (28.282)	
Median	41.67	27.78	52.78	41.67	
Min, Max	0.0, 83.3	0.0, 77.8	8.3, 94.4	0.0, 100.0	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	-4.02 (4.155)	-17.48 (2.842)	-6.42 (3.601)	-20.15 (2.796)	
95% CI [2]	-12.33, 4.28	-23.16, -11.80	-13.56, 0.71	-25.69, -14.61	
Difference (95% CI) in CFB [2]		-13.46 (-22.19, -4.73)		-13.73 (-22.04, -5.42)	
p-value [3]		0.003		0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	38.13 (25.404)	30.15 (19.633)	49.72 (25.628)	39.47 (28.372)	
Median	38.89	26.39	47.22	36.11	
Min, Max	2.8, 80.6	0.0, 86.1	0.0, 97.2	0.0, 100.0	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	-4.81 (4.120)	-13.74 (2.841)	-6.68 (3.771)	-19.54 (2.978)	
95% CI [2]	-13.05, 3.42	-19.42, -8.06	-14.15, 0.79	-25.44, -13.64	
Difference (95% CI) in CFB [2]		-8.93 (-17.50, -0.36)		-12.86 (-21.46, -4.26)	
Hedges'G (95% CI) in CFB		-0.47 (-1.03, 0.06)		-0.51 (-0.91, -0.12)	
p-value [3]		0.041		0.004	
					0.517

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	39.41 (20.669)	38.44 (20.417)	54.20 (22.502)	55.93 (22.834)	
Median	39.58	37.50	52.08	54.17	
Min, Max	0.0, 70.8	0.0, 83.3	12.5, 100.0	8.3, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	33.50 (20.500)	29.83 (19.166)	45.83 (22.139)	43.33 (26.038)	
Median	33.33	29.17	45.83	37.50	
Min, Max	0.0, 79.2	0.0, 75.0	4.2, 91.7	0.0, 100.0	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	-6.39 (3.186)	-9.58 (2.174)	-7.99 (2.546)	-12.53 (2.054)	
95% CI [2]	-12.75, -0.03	-13.91, -5.24	-13.03, -2.95	-16.59, -8.46	
Difference (95% CI) in CFB [2]		-3.19 (-9.87, 3.49)		-4.54 (-10.42, 1.34)	
p-value [3]		0.344		0.129	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	78	
Mean (StdDev)	32.58 (17.939)	25.69 (18.321)	43.50 (24.517)	38.42 (23.714)	
Median	31.25	25.00	37.50	37.50	
Min, Max	0.0, 66.7	0.0, 75.0	0.0, 91.7	0.0, 95.8	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	-5.53 (3.569)	-12.54 (2.339)	-10.77 (2.774)	-18.41 (2.289)	
95% CI [2]	-12.66, 1.60	-17.21, -7.86	-16.26, -5.27	-22.94, -13.87	
Difference (95% CI) in CFB [2]		-7.01 (-14.53, 0.51)		-7.64 (-14.12, -1.16)	
p-value [3]		0.067		0.021	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	35.71 (23.444)	23.91 (20.116)	44.23 (24.005)	39.59 (25.242)	
Median	37.50	20.83	45.83	40.00	
Min, Max	0.0, 75.0	0.0, 79.2	0.0, 91.7	0.0, 95.8	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	-3.82 (3.901)	-17.18 (2.657)	-11.31 (3.353)	-18.19 (2.572)	
95% CI [2]	-11.63, 3.98	-22.50, -11.87	-17.95, -4.67	-23.28, -13.10	
Difference (95% CI) in CFB [2]		-13.36 (-21.52, -5.21)		-6.88 (-14.45, 0.69)	
p-value [3]		0.002		0.075	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	41	78	
Mean (StdDev)	30.43 (22.629)	21.02 (17.788)	42.99 (24.178)	36.65 (25.388)	
Median	29.17	16.67	45.83	33.33	
Min, Max	0.0, 66.7	0.0, 70.8	0.0, 95.8	0.0, 91.7	
C5D1 CFB					
n	21	42	41	76	
LS Mean (StdErr) [2]	-4.76 (3.687)	-18.19 (2.606)	-13.30 (3.477)	-20.71 (2.752)	
95% CI [2]	-12.14, 2.61	-23.40, -12.98	-20.19, -6.41	-26.17, -15.26	
Difference (95% CI) in CFB [2]		-13.43 (-21.18, -5.67)		-7.41 (-15.45, 0.62)	
p-value [3]		<0.001		0.070	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	36.59 (21.503)	21.35 (18.745)	42.74 (26.417)	36.50 (25.399)	
Median	29.17	16.67	37.50	33.33	
Min, Max	4.2, 75.0	0.0, 79.2	0.0, 100.0	0.0, 95.8	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	-2.07 (3.946)	-19.07 (2.699)	-11.94 (3.626)	-21.76 (2.815)	
95% CI [2]	-9.96, 5.82	-24.46, -13.67	-19.13, -4.76	-27.34, -16.19	
Difference (95% CI) in CFB [2]		-17.00 (-25.29, -8.71)		-9.82 (-18.18, -1.46)	
p-value [3]		<0.001		0.022	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	31.06 (21.887)	23.09 (20.681)	41.67 (26.987)	35.61 (27.988)	
Median	31.25	18.75	35.42	33.33	
Min, Max	0.0, 70.8	0.0, 83.3	0.0, 100.0	0.0, 95.8	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	-3.93 (3.963)	-14.50 (2.733)	-11.50 (3.862)	-19.65 (3.050)	
95% CI [2]	-11.85, 3.99	-19.97, -9.04	-19.15, -3.85	-25.70, -13.61	
Difference (95% CI) in CFB [2]		-10.57 (-18.82, -2.33)		-8.15 (-16.95, 0.65)	
Hedges'G (95% CI) in CFB		-0.58 (-1.14, -0.05)		-0.31 (-0.71, 0.07)	
p-value [3]		0.013		0.069	
					0.724

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	47.57 (22.182)	42.69 (18.133)	69.70 (19.028)	62.94 (21.343)	
Median	50.00	41.67	75.00	58.33	
Min, Max	0.0, 83.3	0.0, 75.0	8.3, 100.0	8.3, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	43.67 (19.287)	33.67 (18.208)	59.09 (20.634)	44.41 (18.428)	
Median	41.67	33.33	58.33	41.67	
Min, Max	0.0, 83.3	0.0, 75.0	0.0, 91.7	0.0, 83.3	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	-4.49 (3.367)	-8.55 (2.297)	-9.75 (3.594)	-17.19 (2.899)	
95% CI [2]	-11.21, 2.23	-13.14, -3.97	-16.86, -2.64	-22.92, -11.45	
Difference (95% CI) in CFB [2]		-4.07 (-11.12, 2.99)		-7.44 (-15.73, 0.86)	
p-value [3]		0.255		0.078	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	78	
Mean (StdDev)	39.02 (19.651)	32.47 (16.599)	56.48 (21.752)	42.31 (21.012)	
Median	37.50	29.17	58.33	41.67	
Min, Max	0.0, 66.7	0.0, 66.7	0.0, 100.0	0.0, 91.7	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	-7.85 (5.131)	-9.55 (3.363)	-12.53 (3.856)	-19.81 (3.182)	
95% CI [2]	-18.11, 2.40	-16.27, -2.84	-20.16, -4.89	-26.11, -13.51	
Difference (95% CI) in CFB [2]		-1.70 (-12.51, 9.11)		-7.28 (-16.28, 1.72)	
p-value [3]		0.754		0.112	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	41.67 (22.361)	28.62 (13.339)	58.76 (21.794)	40.64 (22.569)	
Median	41.67	25.00	58.33	33.33	
Min, Max	0.0, 75.0	0.0, 50.0	16.7, 100.0	0.0, 100.0	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	-6.14 (5.085)	-14.86 (3.463)	-9.31 (4.256)	-21.32 (3.265)	
95% CI [2]	-16.32, 4.03	-21.79, -7.94	-17.74, -0.88	-27.79, -14.85	
Difference (95% CI) in CFB [2]		-8.72 (-19.35, 1.91)		-12.01 (-21.62, -2.39)	
p-value [3]		0.106		0.015	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	44	41	78	
Mean (StdDev)	42.03 (25.435)	30.30 (15.780)	57.11 (25.520)	40.17 (21.520)	
Median	33.33	25.00	58.33	33.33	
Min, Max	0.0, 91.7	0.0, 75.0	8.3, 100.0	8.3, 100.0	
C5D1 CFB					
n	21	41	41	76	
LS Mean (StdErr) [2]	-5.99 (5.289)	-12.66 (3.752)	-11.34 (4.027)	-21.53 (3.186)	
95% CI [2]	-16.57, 4.59	-20.17, -5.16	-19.32, -3.37	-27.84, -15.21	
Difference (95% CI) in CFB [2]		-6.67 (-17.85, 4.50)		-10.18 (-19.49, -0.88)	
p-value [3]		0.237		0.032	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	43.48 (22.885)	29.34 (16.398)	54.91 (25.270)	42.41 (24.503)	
Median	33.33	29.17	58.33	33.33	
Min, Max	0.0, 100.0	0.0, 75.0	0.0, 100.0	0.0, 91.7	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	-3.24 (4.826)	-12.25 (3.300)	-12.84 (4.368)	-20.67 (3.391)	
95% CI [2]	-12.88, 6.41	-18.85, -5.66	-21.49, -4.19	-27.39, -13.95	
Difference (95% CI) in CFB [2]		-9.02 (-19.16, 1.12)		-7.83 (-17.90, 2.24)	
p-value [3]		0.080		0.126	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.5a
Change from Baseline in MC-QoL by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	43.56 (22.410)	32.47 (17.635)	56.04 (24.749)	38.53 (22.983)	
Median	41.67	25.00	58.33	33.33	
Min, Max	0.0, 83.3	0.0, 83.3	0.0, 100.0	0.0, 91.7	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	-3.96 (4.966)	-11.35 (3.424)	-11.41 (4.294)	-22.02 (3.391)	
95% CI [2]	-13.89, 5.96	-18.20, -4.51	-19.92, -2.91	-28.74, -15.30	
Difference (95% CI) in CFB [2]		-7.39 (-17.71, 2.94)		-10.61 (-20.40, -0.82)	
Hedges'G (95% CI) in CFB		-0.32 (-0.87, 0.21)		-0.37 (-0.77, 0.02)	
p-value [3]		0.158		0.034	
					0.747

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ism-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	58.12 (15.728)	58.37 (16.894)	57.32 (17.662)	57.28 (15.871)	
Median	54.63	60.19	59.26	56.48	
Min, Max	36.1, 95.4	13.9, 98.1	22.2, 97.2	26.9, 91.7	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	48.83 (13.420)	47.30 (20.063)	49.52 (18.005)	44.17 (17.431)	
Median	48.15	45.37	52.78	43.98	
Min, Max	27.8, 75.0	6.5, 90.7	15.7, 92.6	6.5, 88.9	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	-6.52 (4.141)	-10.52 (2.705)	-7.68 (1.560)	-12.88 (1.133)	
95% CI [2]	-14.92, 1.88	-16.01, -5.04	-10.76, -4.60	-15.12, -10.64	
Difference (95% CI) in CFB [2]		-4.00 (-13.78, 5.77)		-5.20 (-8.95, -1.44)	
p-value [3]		0.412		0.007	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	101	
Mean (StdDev)	46.79 (21.111)	45.62 (18.930)	49.02 (19.188)	39.52 (18.296)	
Median	46.30	44.91	49.07	37.96	
Min, Max	10.2, 88.0	6.5, 93.5	14.8, 88.0	1.9, 88.0	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	-8.10 (3.899)	-12.48 (2.547)	-8.59 (2.010)	-17.16 (1.462)	
95% CI [2]	-16.01, -0.19	-17.65, -7.32	-12.57, -4.62	-20.05, -14.27	
Difference (95% CI) in CFB [2]		-4.39 (-13.59, 4.82)		-8.57 (-13.39, -3.75)	
p-value [3]		0.340		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	45.73 (16.226)	47.30 (19.313)	49.86 (20.025)	39.52 (20.267)	
Median	43.52	47.22	54.63	37.04	
Min, Max	20.4, 72.2	4.6, 90.7	11.1, 87.0	1.9, 88.0	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	-9.06 (4.664)	-12.44 (3.015)	-9.12 (2.214)	-18.51 (1.534)	
95% CI [2]	-18.56, 0.44	-18.58, -6.30	-13.49, -4.74	-21.54, -15.48	
Difference (95% CI) in CFB [2]		-3.38 (-14.27, 7.51)		-9.39 (-14.62, -4.16)	
p-value [3]		0.532		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	98	
Mean (StdDev)	43.32 (14.336)	43.02 (20.374)	48.93 (21.774)	37.82 (20.188)	
Median	41.67	34.26	51.85	35.19	
Min, Max	18.5, 69.4	4.6, 86.1	10.2, 88.0	3.7, 93.5	
C5D1 CFB					
n	12	25	50	93	
LS Mean (StdErr) [2]	-12.12 (4.328)	-14.55 (2.851)	-8.20 (2.344)	-19.84 (1.764)	
95% CI [2]	-20.91, -3.32	-20.34, -8.76	-12.83, -3.57	-23.32, -16.35	
Difference (95% CI) in CFB [2]		-2.44 (-12.49, 7.62)		-11.64 (-17.34, -5.94)	
p-value [3]		0.626		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	41.73 (14.597)	42.80 (21.846)	51.39 (20.862)	36.82 (21.344)	
Median	40.74	41.67	50.93	32.41	
Min, Max	18.5, 64.8	5.6, 89.8	12.0, 89.8	2.8, 92.6	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-13.28 (5.134)	-14.79 (3.295)	-5.86 (2.391)	-20.44 (1.721)	
95% CI [2]	-23.70, -2.85	-21.48, -8.10	-10.58, -1.13	-23.84, -17.03	
Difference (95% CI) in CFB [2]		-1.51 (-13.45, 10.42)		-14.58 (-20.33, -8.83)	
p-value [3]		0.798		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	42.81 (15.931)	44.44 (23.259)	48.19 (22.064)	36.56 (21.051)	
Median	38.89	41.67	50.00	31.02	
Min, Max	16.7, 71.3	6.5, 89.8	12.0, 89.8	0.9, 92.6	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	-7.73 (5.905)	-12.03 (3.817)	-8.78 (2.411)	-19.93 (1.739)	
95% CI [2]	-19.76, 4.29	-19.80, -4.25	-13.55, -4.01	-23.37, -16.49	
Difference (95% CI) in CFB [2]		-4.29 (-18.08, 9.49)		-11.15 (-16.94, -5.37)	
Hedges'G (95% CI) in CFB		-0.22 (-0.98, 0.51)		-0.65 (-1.02, -0.31)	
p-value [3]		0.530		<0.001	
					0.295

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	64.96 (18.234)	64.30 (16.608)	63.69 (17.551)	65.35 (16.002)	
Median	61.11	66.67	63.89	66.67	
Min, Max	38.9, 97.2	16.7, 97.2	13.9, 100.0	22.2, 94.4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	55.56 (18.752)	52.79 (20.862)	55.27 (18.636)	51.84 (17.853)	
Median	50.00	55.56	55.56	52.78	
Min, Max	22.2, 88.9	8.3, 88.9	11.1, 100.0	11.1, 94.4	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	-6.77 (4.982)	-10.82 (3.255)	-8.33 (1.786)	-13.46 (1.298)	
95% CI [2]	-16.88, 3.33	-17.42, -4.22	-11.86, -4.80	-16.03, -10.90	
Difference (95% CI) in CFB [2]		-4.05 (-15.81, 7.71)		-5.13 (-9.43, -0.83)	
p-value [3]		0.490		0.020	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	102	
Mean (StdDev)	54.26 (25.779)	52.35 (21.952)	54.49 (19.735)	47.18 (19.307)	
Median	50.00	52.78	55.56	44.44	
Min, Max	11.1, 100.0	8.3, 91.7	16.7, 97.2	2.8, 95.8	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	-8.42 (5.059)	-11.45 (3.306)	-10.08 (2.201)	-18.42 (1.602)	
95% CI [2]	-18.68, 1.84	-18.16, -4.75	-14.43, -5.73	-21.59, -15.26	
Difference (95% CI) in CFB [2]		-3.03 (-14.97, 8.91)		-8.34 (-13.63, -3.06)	
p-value [3]		0.610		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	55.56 (24.401)	53.82 (21.436)	55.38 (21.937)	47.54 (20.930)	
Median	55.56	56.94	61.11	47.22	
Min, Max	19.4, 97.2	5.6, 94.4	11.1, 94.4	5.6, 91.7	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	-7.69 (5.606)	-11.04 (3.624)	-10.59 (2.491)	-18.26 (1.725)	
95% CI [2]	-19.11, 3.73	-18.42, -3.66	-15.51, -5.66	-21.67, -14.85	
Difference (95% CI) in CFB [2]		-3.35 (-16.44, 9.74)		-7.67 (-13.55, -1.79)	
p-value [3]		0.605		0.011	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	98	
Mean (StdDev)	54.37 (21.398)	48.93 (21.632)	55.67 (22.412)	46.30 (21.300)	
Median	59.72	47.22	58.33	45.83	
Min, Max	19.4, 94.4	5.6, 88.9	11.1, 91.7	2.8, 100.0	
C5D1 CFB					
n	12	25	50	93	
LS Mean (StdErr) [2]	-9.25 (5.109)	-14.33 (3.365)	-8.45 (2.530)	-19.24 (1.904)	
95% CI [2]	-19.63, 1.14	-21.17, -7.49	-13.45, -3.45	-23.00, -15.47	
Difference (95% CI) in CFB [2]		-5.08 (-16.95, 6.78)		-10.79 (-16.94, -4.64)	
p-value [3]		0.390		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	49.40 (21.019)	50.10 (24.695)	57.18 (21.146)	43.63 (21.850)	
Median	44.44	55.56	58.33	41.67	
Min, Max	22.2, 97.2	2.8, 94.4	16.7, 94.4	2.8, 97.2	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-12.51 (5.934)	-13.31 (3.808)	-6.94 (2.598)	-20.78 (1.870)	
95% CI [2]	-24.56, -0.47	-21.04, -5.58	-12.07, -1.80	-24.48, -17.09	
Difference (95% CI) in CFB [2]		-0.79 (-14.59, 13.00)		-13.85 (-20.09, -7.60)	
p-value [3]		0.908		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	49.57 (21.059)	51.22 (23.829)	54.02 (21.095)	44.88 (21.707)	
Median	50.00	50.00	55.56	41.67	
Min, Max	19.4, 97.2	13.9, 94.4	13.9, 88.9	0.0, 100.0	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	-8.21 (6.428)	-11.03 (4.155)	-9.41 (2.610)	-19.65 (1.882)	
95% CI [2]	-21.30, 4.89	-19.49, -2.56	-14.57, -4.25	-23.37, -15.93	
Difference (95% CI) in CFB [2]		-2.82 (-17.83, 12.18)		-10.23 (-16.49, -3.97)	
Hedges'G (95% CI) in CFB		-0.13 (-0.88, 0.60)		-0.55 (-0.91, -0.21)	
p-value [3]		0.704		0.002	
					0.273

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	57.69 (20.100)	55.66 (21.784)	54.77 (23.549)	55.89 (20.924)	
Median	58.33	55.56	52.78	55.56	
Min, Max	16.7, 97.2	5.6, 100.0	13.9, 94.4	5.6, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	49.26 (18.766)	46.30 (22.008)	46.86 (23.577)	42.40 (23.980)	
Median	50.00	44.44	50.00	38.89	
Min, Max	25.0, 83.3	2.8, 100.0	2.8, 91.7	0.0, 100.0	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	-4.56 (4.479)	-9.04 (2.926)	-8.48 (2.078)	-13.68 (1.510)	
95% CI [2]	-13.64, 4.52	-14.97, -3.10	-12.58, -4.37	-16.67, -10.70	
Difference (95% CI) in CFB [2]		-4.48 (-15.05, 6.09)		-5.20 (-10.21, -0.20)	
p-value [3]		0.396		0.042	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	101	
Mean (StdDev)	48.33 (23.983)	44.12 (20.658)	47.38 (23.923)	38.12 (24.089)	
Median	41.67	47.22	45.83	33.33	
Min, Max	8.3, 86.1	2.8, 100.0	5.6, 88.9	0.0, 97.2	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	-4.36 (4.503)	-11.75 (2.942)	-8.20 (2.433)	-17.65 (1.771)	
95% CI [2]	-13.49, 4.77	-17.71, -5.78	-13.01, -3.39	-21.15, -14.15	
Difference (95% CI) in CFB [2]		-7.39 (-18.02, 3.24)		-9.45 (-15.29, -3.62)	
p-value [3]		0.167		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	45.30 (18.921)	47.69 (22.353)	46.69 (24.741)	37.62 (24.806)	
Median	47.22	48.61	47.22	33.33	
Min, Max	19.4, 69.4	2.8, 97.2	2.8, 94.4	0.0, 97.2	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	-5.70 (6.155)	-9.96 (3.979)	-10.57 (2.616)	-19.58 (1.812)	
95% CI [2]	-18.24, 6.84	-18.07, -1.86	-15.74, -5.40	-23.16, -15.99	
Difference (95% CI) in CFB [2]		-4.26 (-18.63, 10.11)		-9.00 (-15.18, -2.83)	
p-value [3]		0.550		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	49	99	
Mean (StdDev)	42.06 (18.804)	42.95 (23.336)	45.75 (25.686)	35.40 (24.846)	
Median	41.67	41.67	47.22	33.33	
Min, Max	11.1, 77.8	0.0, 97.2	0.0, 94.4	0.0, 100.0	
C5D1 CFB					
n	12	25	49	94	
LS Mean (StdErr) [2]	-11.42 (5.283)	-12.06 (3.479)	-8.89 (2.888)	-22.16 (2.138)	
95% CI [2]	-22.15, -0.68	-19.13, -4.99	-14.61, -3.18	-26.38, -17.93	
Difference (95% CI) in CFB [2]		-0.64 (-12.91, 11.63)		-13.26 (-20.26, -6.27)	
p-value [3]		0.916		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	41.67 (18.361)	41.26 (24.127)	50.29 (24.900)	34.97 (26.220)	
Median	43.06	38.89	50.00	30.56	
Min, Max	11.1, 66.7	0.0, 97.2	0.0, 94.4	0.0, 100.0	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-11.93 (5.784)	-13.50 (3.712)	-5.23 (2.863)	-21.81 (2.061)	
95% CI [2]	-23.67, -0.19	-21.04, -5.97	-10.89, 0.44	-25.88, -17.73	
Difference (95% CI) in CFB [2]		-1.58 (-15.02, 11.87)		-16.58 (-23.47, -9.70)	
p-value [3]		0.813		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	44.02 (20.844)	43.67 (27.211)	46.03 (27.317)	33.74 (24.987)	
Median	47.22	44.44	47.22	30.56	
Min, Max	13.9, 80.6	0.0, 100.0	0.0, 97.2	0.0, 100.0	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	-4.78 (6.999)	-10.44 (4.525)	-9.02 (2.856)	-21.84 (2.059)	
95% CI [2]	-19.03, 9.48	-19.66, -1.23	-14.67, -3.37	-25.91, -17.77	
Difference (95% CI) in CFB [2]		-5.66 (-22.00, 10.67)		-12.82 (-19.67, -5.97)	
Hedges'G (95% CI) in CFB		-0.25 (-1.01, 0.48)		-0.63 (-1.00, -0.29)	
p-value [3]		0.485		<0.001	
					0.318

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	47.44 (21.078)	53.40 (24.759)	49.35 (23.424)	48.53 (23.057)	
Median	45.83	58.33	50.00	45.83	
Min, Max	12.5, 100.0	0.0, 100.0	0.0, 100.0	0.0, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	37.22 (13.313)	42.44 (26.706)	42.52 (24.098)	37.58 (23.892)	
Median	37.50	45.83	41.67	33.33	
Min, Max	12.5, 58.3	0.0, 100.0	0.0, 91.7	0.0, 100.0	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	-10.39 (4.665)	-10.77 (3.048)	-5.70 (2.030)	-10.61 (1.475)	
95% CI [2]	-19.85, -0.93	-16.95, -4.58	-9.71, -1.69	-13.53, -7.70	
Difference (95% CI) in CFB [2]		-0.38 (-11.39, 10.63)		-4.91 (-9.80, -0.03)	
p-value [3]		0.945		0.049	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	102	
Mean (StdDev)	34.17 (21.890)	37.98 (23.044)	41.57 (23.272)	32.65 (22.455)	
Median	33.33	37.50	41.67	29.17	
Min, Max	0.0, 79.2	0.0, 95.8	0.0, 91.7	0.0, 95.8	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	-11.30 (4.544)	-14.56 (2.969)	-7.11 (2.335)	-15.54 (1.699)	
95% CI [2]	-20.51, -2.08	-20.59, -8.54	-11.73, -2.50	-18.90, -12.18	
Difference (95% CI) in CFB [2]		-3.27 (-14.00, 7.46)		-8.43 (-14.03, -2.83)	
p-value [3]		0.540		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	30.77 (14.488)	39.41 (20.814)	44.15 (25.340)	32.60 (25.184)	
Median	25.00	41.67	45.83	29.17	
Min, Max	4.2, 54.2	0.0, 83.3	0.0, 91.7	0.0, 95.8	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	-16.07 (4.202)	-16.09 (2.716)	-5.93 (2.801)	-17.09 (1.940)	
95% CI [2]	-24.63, -7.51	-21.62, -10.55	-11.47, -0.39	-20.92, -13.25	
Difference (95% CI) in CFB [2]		-0.01 (-9.82, 9.80)		-11.16 (-17.77, -4.54)	
p-value [3]		0.998		0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	99	
Mean (StdDev)	28.87 (11.724)	35.74 (23.839)	41.17 (26.159)	29.42 (24.008)	
Median	27.08	31.25	45.83	25.00	
Min, Max	4.2, 50.0	0.0, 87.5	0.0, 95.8	0.0, 91.7	
C5D1 CFB					
n	12	25	50	94	
LS Mean (StdErr) [2]	-17.16 (5.246)	-17.16 (3.455)	-7.80 (2.760)	-19.52 (2.060)	
95% CI [2]	-27.82, -6.50	-24.19, -10.14	-13.26, -2.34	-23.59, -15.45	
Difference (95% CI) in CFB [2]		-0.01 (-12.19, 12.18)		-11.72 (-18.42, -5.03)	
p-value [3]		>0.999		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	28.57 (14.605)	34.57 (23.958)	43.92 (26.056)	29.74 (24.367)	
Median	29.17	33.33	47.92	25.00	
Min, Max	0.0, 58.3	0.0, 91.7	0.0, 100.0	0.0, 95.8	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-17.87 (6.198)	-19.05 (3.977)	-4.24 (2.809)	-19.31 (2.022)	
95% CI [2]	-30.45, -5.29	-27.12, -10.97	-9.79, 1.32	-23.31, -15.31	
Difference (95% CI) in CFB [2]		-1.17 (-15.58, 13.23)		-15.07 (-21.82, -8.32)	
p-value [3]		0.869		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	27.88 (17.545)	37.17 (25.963)	40.56 (26.893)	29.04 (25.808)	
Median	29.17	41.67	33.33	22.92	
Min, Max	0.0, 58.3	0.0, 95.8	0.0, 100.0	0.0, 95.8	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	-12.60 (5.947)	-13.33 (3.844)	-8.21 (2.990)	-19.04 (2.155)	
95% CI [2]	-24.72, -0.49	-21.17, -5.50	-14.12, -2.30	-23.30, -14.78	
Difference (95% CI) in CFB [2]		-0.73 (-14.61, 13.15)		-10.83 (-18.00, -3.66)	
Hedges'G (95% CI) in CFB		-0.04 (-0.78, 0.70)		-0.51 (-0.87, -0.17)	
p-value [3]		0.915		0.003	
					0.228

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	60.26 (14.889)	58.64 (17.975)	62.27 (24.261)	54.71 (23.301)	
Median	58.33	58.33	66.67	58.33	
Min, Max	33.3, 83.3	16.7, 91.7	0.0, 100.0	0.0, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	50.56 (20.766)	43.83 (21.754)	54.32 (21.643)	39.62 (18.138)	
Median	50.00	41.67	50.00	33.33	
Min, Max	16.7, 91.7	0.0, 83.3	0.0, 91.7	0.0, 83.3	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	-3.77 (7.177)	-13.34 (4.689)	-7.73 (2.568)	-13.23 (1.866)	
95% CI [2]	-18.32, 10.79	-22.85, -3.83	-12.80, -2.65	-16.91, -9.54	
Difference (95% CI) in CFB [2]		-9.57 (-26.51, 7.37)		-5.50 (-11.68, 0.68)	
p-value [3]		0.260		0.081	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	102	
Mean (StdDev)	45.00 (15.999)	45.19 (19.174)	52.40 (23.933)	36.85 (19.777)	
Median	41.67	45.83	58.33	33.33	
Min, Max	16.7, 75.0	16.7, 75.0	0.0, 100.0	0.0, 91.7	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	-11.95 (6.381)	-13.62 (4.169)	-8.82 (3.285)	-15.16 (2.390)	
95% CI [2]	-24.89, 0.99	-22.08, -5.17	-15.31, -2.32	-19.89, -10.44	
Difference (95% CI) in CFB [2]		-1.67 (-16.74, 13.39)		-6.35 (-14.23, 1.53)	
p-value [3]		0.823		0.114	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	47.44 (19.657)	42.36 (22.778)	54.26 (24.194)	34.92 (19.615)	
Median	41.67	33.33	58.33	33.33	
Min, Max	16.7, 75.0	16.7, 91.7	0.0, 100.0	0.0, 100.0	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	-9.21 (7.142)	-16.76 (4.617)	-7.24 (3.442)	-18.91 (2.384)	
95% CI [2]	-23.76, 5.33	-26.17, -7.36	-14.04, -0.44	-23.62, -14.20	
Difference (95% CI) in CFB [2]		-7.55 (-24.22, 9.12)		-11.67 (-19.80, -3.54)	
p-value [3]		0.363		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	98	
Mean (StdDev)	42.86 (19.019)	40.06 (20.952)	54.17 (27.677)	35.46 (19.818)	
Median	45.83	33.33	58.33	33.33	
Min, Max	8.3, 66.7	0.0, 83.3	0.0, 100.0	8.3, 100.0	
C5D1 CFB					
n	12	25	50	93	
LS Mean (StdErr) [2]	-12.73 (7.075)	-17.47 (4.660)	-6.07 (3.309)	-16.09 (2.490)	
95% CI [2]	-27.11, 1.65	-26.94, -8.00	-12.61, 0.47	-21.02, -11.17	
Difference (95% CI) in CFB [2]		-4.74 (-21.17, 11.69)		-10.02 (-18.07, -1.98)	
p-value [3]		0.561		0.015	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	45.24 (18.407)	41.98 (23.625)	52.26 (26.394)	36.11 (22.198)	
Median	45.83	33.33	54.17	33.33	
Min, Max	8.3, 66.7	0.0, 91.7	0.0, 100.0	0.0, 91.7	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-10.42 (7.556)	-14.58 (4.849)	-8.25 (3.409)	-17.50 (2.453)	
95% CI [2]	-25.76, 4.92	-24.43, -4.74	-14.99, -1.51	-22.35, -12.65	
Difference (95% CI) in CFB [2]		-4.17 (-21.73, 13.40)		-9.25 (-17.44, -1.05)	
p-value [3]		0.633		0.027	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.6a
Change from Baseline in MC-QoL by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	48.72 (21.204)	41.00 (23.313)	52.38 (25.459)	35.05 (20.491)	
Median	50.00	33.33	50.00	33.33	
Min, Max	8.3, 83.3	8.3, 91.7	0.0, 100.0	0.0, 91.7	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	-5.44 (8.349)	-17.17 (5.397)	-7.80 (3.270)	-16.80 (2.358)	
95% CI [2]	-22.45, 11.56	-28.16, -6.18	-14.26, -1.33	-21.47, -12.14	
Difference (95% CI) in CFB [2]		-11.72 (-31.21, 7.77)		-9.01 (-16.85, -1.16)	
Hedges'G (95% CI) in CFB		-0.43 (-1.21, 0.29)		-0.39 (-0.74, -0.04)	
p-value [3]		0.229		0.025	
					0.632

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-tryp-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	56.68 (17.397)	56.88 (16.076)	70.14 (4.863)	65.19 (13.790)	
Median	56.48	56.48	72.22	61.57	
Min, Max	22.2, 97.2	13.9, 98.1	63.0, 73.1	46.3, 87.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	48.53 (17.005)	44.15 (17.915)	62.96 (11.809)	53.81 (16.785)	
Median	49.07	43.52	59.26	54.63	
Min, Max	15.7, 92.6	6.5, 90.7	53.7, 79.6	25.9, 84.3	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	-6.82 (1.639)	-11.99 (1.258)	-13.37 (9.131)	-13.56 (6.954)	
95% CI [2]	-10.05, -3.58	-14.48, -9.51	-34.02, 7.29	-29.29, 2.17	
Difference (95% CI) in CFB [2]		-5.18 (-8.78, -1.57)		-0.19 (-17.47, 17.09)	
p-value [3]		0.005		0.981	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	118	4	9	
Mean (StdDev)	47.86 (19.741)	40.14 (18.342)	59.03 (12.176)	49.07 (19.913)	
Median	48.15	37.50	58.80	38.89	
Min, Max	10.2, 88.0	1.9, 93.5	47.2, 71.3	25.9, 80.6	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-7.38 (1.975)	-15.47 (1.499)	-10.73 (10.964)	-14.79 (8.350)	
95% CI [2]	-11.28, -3.48	-18.42, -12.51	-35.53, 14.07	-33.68, 4.09	
Difference (95% CI) in CFB [2]		-8.09 (-12.45, -3.73)		-4.07 (-24.82, 16.68)	
p-value [3]		<0.001		0.668	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	47.62 (19.129)	39.81 (19.823)	67.82 (6.607)	54.72 (21.238)	
Median	43.98	37.96	69.91	52.78	
Min, Max	11.1, 87.0	1.9, 90.7	58.3, 73.1	18.5, 81.5	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-8.39 (2.210)	-16.63 (1.640)	-2.09 (12.252)	-10.82 (9.380)	
95% CI [2]	-12.75, -4.02	-19.87, -13.40	-29.39, 25.21	-31.72, 10.08	
Difference (95% CI) in CFB [2]		-8.25 (-13.04, -3.46)		-8.73 (-31.40, 13.94)	
p-value [3]		<0.001		0.411	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	114	4	10	
Mean (StdDev)	46.65 (20.576)	37.74 (19.595)	63.43 (8.469)	52.31 (23.860)	
Median	46.36	33.33	63.89	50.46	
Min, Max	10.2, 88.0	3.7, 93.5	52.8, 73.1	20.4, 84.3	
C5D1 CFB					
n	58	108	4	10	
LS Mean (StdErr) [2]	-8.29 (2.312)	-18.49 (1.790)	-8.57 (12.624)	-15.91 (9.665)	
95% CI [2]	-12.85, -3.72	-22.03, -14.96	-36.70, 19.55	-37.45, 5.62	
Difference (95% CI) in CFB [2]		-10.20 (-15.31, -5.09)		-7.34 (-30.70, 16.02)	
p-value [3]		<0.001		0.500	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	48.00 (19.965)	36.82 (21.073)	66.67 (8.453)	52.96 (22.058)	
Median	47.69	33.33	68.98	55.09	
Min, Max	12.0, 89.8	2.8, 92.6	54.6, 74.1	21.3, 82.4	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-6.81 (2.419)	-19.25 (1.815)	3.28 (11.743)	-8.11 (8.991)	
95% CI [2]	-11.59, -2.03	-22.83, -15.67	-22.89, 29.44	-28.14, 11.92	
Difference (95% CI) in CFB [2]		-12.44 (-17.78, -7.10)		-11.39 (-33.11, 10.34)	
p-value [3]		<0.0001		0.270	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	45.93 (21.121)	36.97 (21.124)	63.43 (6.783)	51.48 (24.240)	
Median	45.37	31.48	65.74	49.54	
Min, Max	12.0, 89.8	0.9, 91.7	53.7, 68.5	16.7, 92.6	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-6.86 (2.537)	-17.11 (1.916)	-3.00 (11.486)	-12.33 (8.794)	
95% CI [2]	-11.87, -1.85	-20.89, -13.32	-28.59, 22.59	-31.92, 7.27	
Difference (95% CI) in CFB [2]		-10.24 (-15.77, -4.72)		-9.33 (-30.58, 11.92)	
Hedges'G (95% CI) in CFB		-0.52 (-0.85, -0.19)		-0.33 (-1.69, 0.90)	
p-value [3]		<0.001		0.351	
					0.720

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	62.76 (17.356)	64.78 (16.436)	82.64 (7.649)	69.72 (9.838)	
Median	62.50	66.67	81.94	72.22	
Min, Max	13.9, 100.0	16.7, 97.2	75.0, 91.7	55.6, 80.6	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	54.25 (18.204)	51.72 (18.463)	72.92 (16.414)	56.48 (18.002)	
Median	52.78	52.78	66.67	55.56	
Min, Max	11.1, 100.0	8.3, 94.4	61.1, 97.2	25.0, 80.6	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	-7.34 (1.907)	-12.29 (1.463)	-20.23 (10.237)	-20.29 (7.796)	
95% CI [2]	-11.10, -3.57	-15.17, -9.40	-43.39, 2.93	-37.93, -2.65	
Difference (95% CI) in CFB [2]		-4.95 (-9.14, -0.75)		-0.06 (-19.44, 19.31)	
p-value [3]		0.021		0.995	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	119	4	9	
Mean (StdDev)	53.66 (20.774)	47.82 (20.094)	66.67 (24.322)	53.70 (17.010)	
Median	55.56	47.22	62.50	58.33	
Min, Max	11.1, 100.0	2.8, 95.8	44.4, 97.2	22.2, 72.2	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-7.86 (2.246)	-15.68 (1.704)	-15.34 (12.144)	-15.61 (9.248)	
95% CI [2]	-12.29, -3.43	-19.04, -12.32	-42.81, 12.13	-36.53, 5.31	
Difference (95% CI) in CFB [2]		-7.82 (-12.78, -2.86)		-0.27 (-23.26, 22.71)	
p-value [3]		0.002		0.979	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	53.52 (21.585)	47.92 (21.217)	81.94 (14.611)	58.06 (17.736)	
Median	54.17	47.22	86.11	58.33	
Min, Max	11.1, 97.2	5.6, 94.4	61.1, 94.4	33.3, 83.3	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-8.99 (2.522)	-15.53 (1.872)	1.39 (13.806)	-9.72 (10.571)	
95% CI [2]	-13.97, -4.01	-19.23, -11.83	-29.37, 32.15	-33.28, 13.83	
Difference (95% CI) in CFB [2]		-6.54 (-12.01, -1.08)		-11.11 (-36.66, 14.44)	
p-value [3]		0.019		0.355	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	114	4	10	
Mean (StdDev)	54.13 (21.899)	46.24 (21.325)	74.31 (15.937)	53.89 (20.878)	
Median	58.33	44.44	76.39	54.17	
Min, Max	11.1, 94.4	2.8, 100.0	55.6, 88.9	22.2, 83.3	
C5D1 CFB					
n	58	108	4	10	
LS Mean (StdErr) [2]	-7.69 (2.537)	-17.50 (1.964)	-12.24 (13.248)	-21.24 (10.143)	
95% CI [2]	-12.70, -2.68	-21.38, -13.62	-41.76, 17.27	-43.84, 1.35	
Difference (95% CI) in CFB [2]		-9.81 (-15.42, -4.20)		-9.00 (-33.51, 15.51)	
p-value [3]		<0.001		0.432	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	53.64 (20.579)	44.42 (22.727)	81.25 (11.867)	51.67 (19.824)	
Median	52.78	41.67	86.11	58.33	
Min, Max	16.7, 97.2	2.8, 97.2	63.9, 88.9	25.0, 75.0	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-7.28 (2.674)	-18.25 (2.006)	4.78 (13.390)	-14.04 (10.252)	
95% CI [2]	-12.57, -2.00	-22.21, -14.29	-25.05, 34.62	-36.89, 8.80	
Difference (95% CI) in CFB [2]		-10.97 (-16.87, -5.07)		-18.83 (-43.60, 5.95)	
p-value [3]		<0.001		0.121	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	51.82 (20.888)	45.35 (22.213)	71.53 (13.679)	55.28 (20.764)	
Median	52.78	41.67	70.83	58.33	
Min, Max	13.9, 97.2	0.0, 100.0	55.6, 88.9	25.0, 86.1	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-7.27 (2.757)	-16.58 (2.082)	-10.03 (13.374)	-14.51 (10.240)	
95% CI [2]	-12.72, -1.83	-20.69, -12.47	-39.83, 19.77	-37.32, 8.31	
Difference (95% CI) in CFB [2]		-9.30 (-15.31, -3.30)		-4.48 (-29.22, 20.27)	
Hedges'G (95% CI) in CFB		-0.43 (-0.76, -0.11)		-0.13 (-1.45, 1.13)	
p-value [3]		0.003		0.695	
					0.560

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	53.79 (22.438)	55.09 (21.128)	79.86 (14.232)	65.28 (17.871)	
Median	52.78	55.56	81.94	63.89	
Min, Max	13.9, 97.2	5.6, 100.0	61.1, 94.4	27.8, 94.4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	46.03 (22.363)	42.43 (23.593)	69.44 (11.340)	53.70 (21.916)	
Median	47.22	38.89	65.28	55.56	
Min, Max	2.8, 91.7	0.0, 100.0	61.1, 86.1	16.7, 94.4	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	-6.55 (2.101)	-11.87 (1.612)	-11.78 (11.282)	-9.21 (8.592)	
95% CI [2]	-10.70, -2.41	-15.05, -8.69	-37.30, 13.75	-28.65, 10.23	
Difference (95% CI) in CFB [2]		-5.32 (-9.94, -0.70)		2.57 (-18.79, 23.92)	
p-value [3]		0.024		0.792	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	118	4	9	
Mean (StdDev)	46.21 (23.793)	38.77 (23.239)	69.44 (6.415)	46.91 (26.696)	
Median	41.67	36.11	69.44	50.00	
Min, Max	5.6, 88.9	0.0, 100.0	63.9, 75.0	13.9, 94.4	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-6.04 (2.384)	-15.16 (1.809)	-12.80 (12.062)	-19.72 (9.186)	
95% CI [2]	-10.75, -1.34	-18.73, -11.59	-40.09, 14.48	-40.50, 1.06	
Difference (95% CI) in CFB [2]		-9.11 (-14.38, -3.85)		-6.91 (-29.74, 15.91)	
p-value [3]		<0.001		0.511	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	44.54 (23.162)	38.14 (23.966)	72.22 (6.001)	55.56 (27.685)	
Median	45.83	36.11	70.83	52.78	
Min, Max	2.8, 94.4	0.0, 97.2	66.7, 80.6	11.1, 94.4	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-7.79 (2.710)	-16.08 (2.011)	-13.01 (12.316)	-15.84 (9.430)	
95% CI [2]	-13.14, -2.44	-20.05, -12.11	-40.46, 14.43	-36.85, 5.17	
Difference (95% CI) in CFB [2]		-8.29 (-14.17, -2.42)		-2.83 (-25.62, 19.96)	
p-value [3]		0.006		0.788	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	59	115	4	10	
Mean (StdDev)	43.08 (23.786)	35.37 (23.340)	72.22 (11.785)	55.28 (32.564)	
Median	41.67	33.33	73.61	56.94	
Min, Max	0.0, 94.4	0.0, 100.0	58.3, 83.3	8.3, 97.2	
C5D1 CFB					
n	57	109	4	10	
LS Mean (StdErr) [2]	-7.78 (2.836)	-19.14 (2.179)	-13.27 (15.051)	-16.82 (11.524)	
95% CI [2]	-13.38, -2.18	-23.45, -14.84	-46.81, 20.26	-42.50, 8.86	
Difference (95% CI) in CFB [2]		-11.37 (-17.63, -5.10)		-3.55 (-31.40, 24.30)	
p-value [3]		<0.001		0.782	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	46.70 (23.538)	34.57 (25.161)	72.22 (10.143)	56.67 (26.261)	
Median	45.83	30.56	72.22	51.39	
Min, Max	0.0, 94.4	0.0, 100.0	61.1, 83.3	16.7, 94.4	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-5.34 (2.882)	-19.92 (2.162)	-1.70 (11.706)	-6.17 (8.962)	
95% CI [2]	-11.03, 0.36	-24.18, -15.65	-27.78, 24.38	-26.14, 13.80	
Difference (95% CI) in CFB [2]		-14.58 (-20.94, -8.22)		-4.48 (-26.14, 17.18)	
p-value [3]		<0.0001		0.655	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	43.68 (25.680)	34.31 (24.964)	73.61 (6.612)	51.94 (29.164)	
Median	44.44	30.56	73.61	48.61	
Min, Max	0.0, 97.2	0.0, 100.0	66.7, 80.6	11.1, 97.2	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-5.69 (3.037)	-17.50 (2.293)	-5.86 (10.899)	-15.90 (8.345)	
95% CI [2]	-11.68, 0.31	-22.03, -12.97	-30.15, 18.42	-34.49, 2.70	
Difference (95% CI) in CFB [2]		-11.81 (-18.43, -5.20)		-10.03 (-30.20, 10.14)	
Hedges'G (95% CI) in CFB		-0.50 (-0.83, -0.17)		-0.37 (-1.75, 0.85)	
p-value [3]		<0.001		0.294	
					0.729

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	48.85 (23.501)	48.50 (23.448)	51.04 (7.887)	62.08 (19.588)	
Median	47.92	45.83	47.92	56.25	
Min, Max	0.0, 100.0	0.0, 100.0	45.8, 62.5	33.3, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	40.90 (22.713)	37.43 (23.961)	48.96 (10.417)	54.17 (27.402)	
Median	41.67	33.33	47.92	66.67	
Min, Max	0.0, 91.7	0.0, 100.0	37.5, 62.5	8.3, 91.7	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	-6.66 (2.060)	-11.11 (1.580)	-13.32 (11.623)	-13.86 (8.852)	
95% CI [2]	-10.73, -2.60	-14.23, -7.99	-39.61, 12.98	-33.88, 6.17	
Difference (95% CI) in CFB [2]		-4.44 (-8.98, 0.09)		-0.54 (-22.54, 21.46)	
p-value [3]		0.055		0.957	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	119	4	9	
Mean (StdDev)	39.80 (23.697)	32.85 (22.087)	41.67 (6.804)	45.37 (27.199)	
Median	37.50	33.33	41.67	41.67	
Min, Max	0.0, 91.7	0.0, 95.8	33.3, 50.0	8.3, 91.7	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-7.75 (2.305)	-15.58 (1.749)	-7.88 (11.863)	-14.18 (9.034)	
95% CI [2]	-12.29, -3.20	-19.03, -12.13	-34.72, 18.95	-34.61, 6.26	
Difference (95% CI) in CFB [2]		-7.83 (-12.92, -2.74)		-6.30 (-28.75, 16.16)	
p-value [3]		0.003		0.542	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	40.48 (24.370)	32.37 (23.311)	52.08 (15.404)	51.67 (32.107)	
Median	39.58	29.17	45.83	56.25	
Min, Max	0.0, 91.7	0.0, 95.8	41.7, 75.0	0.0, 95.8	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-9.03 (2.670)	-18.04 (1.982)	5.40 (15.678)	-8.64 (12.004)	
95% CI [2]	-14.31, -3.76	-21.95, -14.12	-29.53, 40.33	-35.39, 18.10	
Difference (95% CI) in CFB [2]		-9.00 (-14.79, -3.21)		-14.04 (-43.05, 14.97)	
p-value [3]		0.002		0.306	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	115	4	10	
Mean (StdDev)	38.19 (24.860)	29.06 (23.037)	42.71 (11.968)	50.00 (27.847)	
Median	37.50	25.00	39.58	50.00	
Min, Max	0.0, 95.8	0.0, 91.7	33.3, 58.3	8.3, 91.7	
C5D1 CFB					
n	58	109	4	10	
LS Mean (StdErr) [2]	-10.14 (2.742)	-20.08 (2.115)	-1.39 (13.825)	-9.03 (10.585)	
95% CI [2]	-15.55, -4.72	-24.26, -15.91	-32.19, 29.42	-32.61, 14.56	
Difference (95% CI) in CFB [2]		-9.94 (-16.00, -3.89)		-7.64 (-33.22, 17.94)	
p-value [3]		0.001		0.521	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	39.94 (24.927)	29.13 (23.410)	47.92 (22.948)	50.00 (27.287)	
Median	37.50	25.00	45.83	43.75	
Min, Max	0.0, 100.0	0.0, 91.7	25.0, 75.0	8.3, 95.8	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-7.88 (2.827)	-20.81 (2.121)	6.79 (15.578)	-5.86 (11.928)	
95% CI [2]	-13.46, -2.29	-25.00, -16.62	-27.92, 41.50	-32.44, 20.71	
Difference (95% CI) in CFB [2]		-12.93 (-19.17, -6.69)		-12.65 (-41.48, 16.17)	
p-value [3]		<0.0001		0.351	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	37.28 (26.067)	29.13 (24.985)	46.88 (18.122)	48.33 (31.562)	
Median	33.33	25.00	47.92	45.83	
Min, Max	0.0, 100.0	0.0, 95.8	29.2, 62.5	4.2, 95.8	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-8.30 (3.007)	-17.49 (2.270)	8.33 (14.484)	-6.25 (11.089)	
95% CI [2]	-14.24, -2.36	-21.97, -13.01	-23.94, 40.61	-30.96, 18.46	
Difference (95% CI) in CFB [2]		-9.19 (-15.74, -2.64)		-14.58 (-41.38, 12.22)	
Hedges'G (95% CI) in CFB		-0.39 (-0.72, -0.07)		-0.41 (-1.79, 0.81)	
p-value [3]		0.006		0.253	
					0.976

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	63.15 (21.455)	55.33 (22.311)	41.67 (35.355)	57.50 (23.717)	
Median	66.67	58.33	45.83	58.33	
Min, Max	8.3, 100.0	0.0, 100.0	0.0, 75.0	16.7, 91.7	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	54.23 (20.525)	40.10 (18.874)	41.67 (34.021)	45.37 (19.593)	
Median	50.00	41.67	41.67	50.00	
Min, Max	0.0, 91.7	0.0, 83.3	0.0, 83.3	16.7, 83.3	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	-6.59 (2.725)	-13.08 (2.091)	2.36 (17.486)	-5.80 (13.317)	
95% CI [2]	-11.96, -1.21	-17.20, -8.95	-37.20, 41.91	-35.92, 24.33	
Difference (95% CI) in CFB [2]		-6.49 (-12.49, -0.50)		-8.15 (-41.25, 24.94)	
p-value [3]		0.034		0.591	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	119	4	9	
Mean (StdDev)	51.46 (22.025)	37.75 (19.941)	39.58 (30.713)	49.07 (16.375)	
Median	50.00	33.33	41.67	58.33	
Min, Max	0.0, 100.0	0.0, 91.7	0.0, 75.0	25.0, 66.7	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-9.57 (3.260)	-15.48 (2.473)	3.62 (14.538)	1.18 (11.072)	
95% CI [2]	-16.01, -3.14	-20.36, -10.60	-29.26, 36.51	-23.87, 26.22	
Difference (95% CI) in CFB [2]		-5.91 (-13.10, 1.29)		-2.45 (-29.96, 25.07)	
p-value [3]		0.107		0.845	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	53.42 (22.348)	35.29 (19.996)	43.75 (37.500)	48.33 (21.802)	
Median	58.33	33.33	41.67	37.50	
Min, Max	16.7, 100.0	0.0, 100.0	0.0, 91.7	25.0, 83.3	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-7.47 (3.423)	-18.75 (2.540)	5.25 (19.147)	-3.40 (14.659)	
95% CI [2]	-14.23, -0.71	-23.76, -13.73	-37.41, 47.91	-36.06, 29.27	
Difference (95% CI) in CFB [2]		-11.28 (-18.70, -3.86)		-8.64 (-44.07, 26.79)	
p-value [3]		0.003		0.599	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	114	4	10	
Mean (StdDev)	52.08 (26.066)	35.82 (19.737)	45.83 (33.679)	43.33 (23.505)	
Median	54.17	33.33	54.17	37.50	
Min, Max	8.3, 100.0	0.0, 100.0	0.0, 75.0	16.7, 91.7	
C5D1 CFB					
n	58	108	4	10	
LS Mean (StdErr) [2]	-7.94 (3.353)	-16.97 (2.596)	2.16 (18.135)	-10.96 (13.885)	
95% CI [2]	-14.56, -1.32	-22.09, -11.84	-38.25, 42.57	-41.89, 19.98	
Difference (95% CI) in CFB [2]		-9.03 (-16.44, -1.61)		-13.12 (-46.67, 20.44)	
p-value [3]		0.017		0.404	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	51.15 (24.703)	36.13 (21.651)	43.75 (29.950)	51.67 (28.814)	
Median	50.00	33.33	54.17	54.17	
Min, Max	0.0, 100.0	0.0, 91.7	0.0, 66.7	8.3, 91.7	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-8.04 (3.428)	-17.04 (2.571)	6.64 (18.078)	-0.62 (13.841)	
95% CI [2]	-14.81, -1.28	-22.12, -11.96	-33.64, 46.92	-31.46, 30.22	
Difference (95% CI) in CFB [2]		-9.00 (-16.56, -1.43)		-7.25 (-40.70, 26.20)	
p-value [3]		0.020		0.639	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.7a
Change from Baseline in MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	52.30 (24.273)	35.47 (20.505)	41.67 (29.659)	45.00 (26.989)	
Median	50.00	33.33	50.00	41.67	
Min, Max	0.0, 100.0	0.0, 91.7	0.0, 66.7	8.3, 91.7	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-6.66 (3.468)	-16.65 (2.619)	4.01 (18.294)	-7.25 (14.007)	
95% CI [2]	-13.51, 0.19	-21.82, -11.48	-36.75, 44.77	-38.46, 23.96	
Difference (95% CI) in CFB [2]		-9.99 (-17.54, -2.44)		-11.27 (-45.12, 22.59)	
Hedges'G (95% CI) in CFB		-0.37 (-0.70, -0.05)		-0.25 (-1.59, 0.99)	
p-value [3]		0.010		0.475	
					0.993

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-ecog-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	56.48 (6.547)	68.06 (14.458)	57.53 (17.678)	56.65 (15.891)	
Median	57.41	73.61	56.94	56.48	
Min, Max	48.1, 63.0	40.7, 81.5	22.2, 97.2	13.9, 98.1	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	44.21 (8.329)	52.04 (22.062)	49.69 (17.405)	44.21 (17.560)	
Median	44.91	53.24	52.78	43.52	
Min, Max	34.3, 52.8	21.3, 85.2	15.7, 92.6	6.5, 90.7	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	-15.33 (7.827)	-22.32 (7.827)	-6.31 (1.624)	-11.37 (1.243)	
95% CI [2]	-32.77, 2.11	-39.76, -4.88	-9.52, -3.11	-13.82, -8.91	
Difference (95% CI) in CFB [2]		-6.99 (-29.17, 15.19)		-5.05 (-8.60, -1.51)	
p-value [3]		0.499		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	117	
Mean (StdDev)	45.14 (14.956)	47.22 (22.274)	48.74 (19.820)	40.22 (18.167)	
Median	44.91	44.44	49.07	37.96	
Min, Max	27.8, 63.0	23.1, 88.0	10.2, 88.0	1.9, 93.5	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	-13.03 (9.907)	-24.63 (9.907)	-7.32 (1.963)	-14.87 (1.486)	
95% CI [2]	-35.10, 9.05	-46.70, -2.55	-11.20, -3.45	-17.81, -11.94	
Difference (95% CI) in CFB [2]		-11.60 (-39.68, 16.48)		-7.55 (-11.85, -3.25)	
p-value [3]		0.379		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	40.43 (18.387)	40.74 (19.422)	49.42 (19.307)	40.98 (20.387)	
Median	44.44	30.56	47.22	39.35	
Min, Max	20.4, 56.5	18.5, 74.1	11.1, 87.0	1.9, 90.7	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	-26.62 (11.795)	-31.02 (8.847)	-7.34 (2.188)	-15.25 (1.636)	
95% CI [2]	-53.82, 0.58	-51.42, -10.62	-11.66, -3.02	-18.48, -12.02	
Difference (95% CI) in CFB [2]		-4.40 (-35.56, 26.76)		-7.91 (-12.63, -3.18)	
p-value [3]		0.753		0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	116	
Mean (StdDev)	39.12 (16.827)	37.15 (18.415)	48.27 (20.619)	39.03 (20.444)	
Median	44.44	33.80	48.61	35.19	
Min, Max	15.7, 51.9	18.5, 74.1	10.2, 88.0	3.7, 93.5	
C5D1 CFB					
n	4	8	58	110	
LS Mean (StdErr) [2]	-19.12 (10.362)	-28.10 (10.362)	-7.63 (2.310)	-17.26 (1.775)	
95% CI [2]	-43.02, 4.77	-51.99, -4.20	-12.19, -3.07	-20.77, -13.76	
Difference (95% CI) in CFB [2]		-8.97 (-39.54, 21.59)		-9.63 (-14.67, -4.59)	
p-value [3]		0.517		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	40.51 (15.501)	37.24 (22.091)	49.81 (20.171)	38.13 (21.552)	
Median	44.44	29.63	50.00	34.72	
Min, Max	18.5, 54.6	13.9, 74.1	12.0, 89.8	2.8, 92.6	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-17.42 (10.815)	-30.42 (10.815)	-5.93 (2.412)	-17.86 (1.799)	
95% CI [2]	-41.88, 7.05	-54.89, -5.96	-10.70, -1.17	-21.42, -14.31	
Difference (95% CI) in CFB [2]		-13.00 (-44.20, 18.19)		-11.93 (-17.19, -6.67)	
p-value [3]		0.370		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Total Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	41.90 (20.221)	27.89 (12.986)	47.41 (21.097)	38.80 (21.963)	
Median	47.22	24.07	47.69	36.11	
Min, Max	13.9, 59.3	13.9, 48.1	12.0, 89.8	0.9, 92.6	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-15.08 (9.928)	-38.01 (9.928)	-6.34 (2.495)	-15.35 (1.874)	
95% CI [2]	-37.97, 7.82	-60.90, -15.12	-11.26, -1.41	-19.05, -11.65	
Difference (95% CI) in CFB [2]		-22.93 (-52.22, 6.35)		-9.01 (-14.37, -3.65)	
Hedges'G (95% CI) in CFB		-0.82 (-2.45, 0.41)		-0.46 (-0.79, -0.14)	
p-value [3]		0.109		0.001	
					0.267

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	56.25 (7.649)	73.33 (13.808)	64.41 (17.913)	64.49 (16.103)	
Median	56.94	76.39	63.89	66.67	
Min, Max	47.2, 63.9	47.2, 91.7	13.9, 100.0	16.7, 97.2	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	45.83 (3.586)	59.17 (25.528)	55.91 (18.920)	51.47 (17.742)	
Median	45.83	59.72	55.56	52.78	
Min, Max	41.7, 50.0	11.1, 91.7	11.1, 100.0	8.3, 94.4	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	-15.62 (10.618)	-26.05 (10.618)	-6.96 (1.841)	-11.90 (1.409)	
95% CI [2]	-39.28, 8.04	-49.71, -2.39	-10.59, -3.33	-14.68, -9.13	
Difference (95% CI) in CFB [2]		-10.43 (-40.52, 19.66)		-4.94 (-8.96, -0.93)	
p-value [3]		0.458		0.016	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	118	
Mean (StdDev)	47.22 (9.886)	54.17 (20.962)	54.89 (21.498)	47.73 (19.810)	
Median	45.83	48.61	55.56	47.22	
Min, Max	38.9, 58.3	27.8, 88.9	11.1, 100.0	2.8, 95.8	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	-11.81 (9.537)	-28.00 (9.537)	-8.06 (2.249)	-15.15 (1.703)	
95% CI [2]	-33.06, 9.44	-49.25, -6.76	-12.50, -3.62	-18.52, -11.79	
Difference (95% CI) in CFB [2]		-16.19 (-43.22, 10.83)		-7.10 (-12.03, -2.17)	
p-value [3]		0.211		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	39.81 (13.981)	52.78 (20.647)	56.24 (22.409)	48.40 (21.169)	
Median	41.67	47.22	61.11	48.61	
Min, Max	25.0, 52.8	30.6, 91.7	11.1, 97.2	5.6, 94.4	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	-32.81 (11.990)	-30.12 (8.992)	-7.31 (2.498)	-14.42 (1.868)	
95% CI [2]	-60.46, -5.16	-50.86, -9.39	-12.25, -2.38	-18.11, -10.73	
Difference (95% CI) in CFB [2]		2.69 (-28.98, 34.37)		-7.11 (-12.51, -1.71)	
p-value [3]		0.850		0.010	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	116	
Mean (StdDev)	37.50 (11.226)	51.39 (18.306)	56.58 (22.109)	46.54 (21.534)	
Median	40.28	44.44	61.11	45.83	
Min, Max	22.2, 47.2	30.6, 86.1	11.1, 94.4	2.8, 100.0	
C5D1 CFB					
n	4	8	58	110	
LS Mean (StdErr) [2]	-21.44 (10.553)	-24.86 (10.553)	-6.90 (2.548)	-16.91 (1.958)	
95% CI [2]	-45.77, 2.90	-49.19, -0.52	-11.94, -1.87	-20.78, -13.05	
Difference (95% CI) in CFB [2]		-3.42 (-34.55, 27.71)		-10.01 (-15.57, -4.45)	
p-value [3]		0.806		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	37.50 (10.269)	45.06 (26.050)	56.66 (21.244)	44.98 (22.368)	
Median	38.89	38.89	55.56	44.44	
Min, Max	25.0, 47.2	16.7, 91.7	16.7, 97.2	2.8, 97.2	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-21.64 (12.562)	-32.99 (12.562)	-5.77 (2.634)	-17.28 (1.965)	
95% CI [2]	-50.06, 6.78	-61.41, -4.57	-10.97, -0.57	-21.16, -13.40	
Difference (95% CI) in CFB [2]		-11.35 (-47.59, 24.88)		-11.51 (-17.25, -5.76)	
p-value [3]		0.496		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Symptoms

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	40.28 (17.198)	38.54 (17.533)	53.98 (21.066)	46.64 (22.433)	
Median	44.44	37.50	54.17	41.67	
Min, Max	16.7, 55.6	13.9, 72.2	13.9, 97.2	0.0, 100.0	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-17.49 (12.541)	-37.14 (12.541)	-6.81 (2.712)	-15.18 (2.036)	
95% CI [2]	-46.41, 11.43	-66.06, -8.22	-12.16, -1.45	-19.20, -11.15	
Difference (95% CI) in CFB [2]		-19.66 (-56.65, 17.34)		-8.37 (-14.19, -2.54)	
Hedges'G (95% CI) in CFB		-0.55 (-2.09, 0.70)		-0.39 (-0.72, -0.07)	
p-value [3]		0.255		0.005	
					0.636

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	60.42 (8.893)	67.78 (21.122)	55.01 (23.414)	54.89 (20.797)	
Median	63.89	70.83	52.78	55.56	
Min, Max	47.2, 66.7	27.8, 88.9	13.9, 97.2	5.6, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	42.36 (12.293)	55.28 (26.978)	47.69 (23.014)	42.21 (23.140)	
Median	41.67	51.39	50.00	38.89	
Min, Max	30.6, 55.6	16.7, 91.7	2.8, 91.7	0.0, 100.0	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	-20.85 (5.993)	-18.96 (5.993)	-5.70 (2.133)	-11.29 (1.632)	
95% CI [2]	-34.20, -7.50	-32.32, -5.61	-9.90, -1.49	-14.51, -8.07	
Difference (95% CI) in CFB [2]		1.89 (-15.10, 18.87)		-5.59 (-10.24, -0.94)	
p-value [3]		0.810		0.019	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	117	
Mean (StdDev)	47.22 (18.002)	50.00 (30.146)	47.62 (24.190)	38.44 (22.749)	
Median	48.61	45.83	44.44	36.11	
Min, Max	27.8, 63.9	11.1, 94.4	5.6, 88.9	0.0, 100.0	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	-12.94 (9.798)	-18.54 (9.798)	-5.99 (2.414)	-15.07 (1.828)	
95% CI [2]	-34.77, 8.89	-40.38, 3.29	-10.76, -1.23	-18.68, -11.47	
Difference (95% CI) in CFB [2]		-5.61 (-33.38, 22.16)		-9.08 (-14.37, -3.79)	
p-value [3]		0.662		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	38.89 (18.215)	38.89 (28.868)	46.78 (23.767)	39.54 (24.391)	
Median	36.11	27.78	47.22	37.50	
Min, Max	22.2, 58.3	5.6, 83.3	2.8, 94.4	0.0, 97.2	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	-31.42 (11.200)	-34.29 (8.400)	-7.00 (2.676)	-14.54 (2.002)	
95% CI [2]	-57.25, -5.60	-53.66, -14.92	-12.28, -1.72	-18.49, -10.59	
Difference (95% CI) in CFB [2]		-2.86 (-32.45, 26.72)		-7.54 (-13.32, -1.76)	
p-value [3]		0.829		0.011	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	59	117	
Mean (StdDev)	36.81 (15.445)	34.72 (26.016)	45.48 (24.710)	37.12 (24.654)	
Median	43.06	30.56	47.22	36.11	
Min, Max	13.9, 47.2	5.6, 83.3	0.0, 94.4	0.0, 100.0	
C5D1 CFB					
n	4	8	57	111	
LS Mean (StdErr) [2]	-24.39 (9.399)	-29.31 (9.399)	-6.86 (2.886)	-17.56 (2.202)	
95% CI [2]	-46.07, -2.72	-50.98, -7.64	-12.56, -1.16	-21.91, -13.21	
Difference (95% CI) in CFB [2]		-4.91 (-32.64, 22.81)		-10.70 (-17.00, -4.41)	
p-value [3]		0.693		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	39.58 (16.257)	37.96 (30.682)	48.95 (24.137)	36.16 (25.578)	
Median	43.06	22.22	48.61	33.33	
Min, Max	19.4, 52.8	8.3, 86.1	0.0, 94.4	0.0, 100.0	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-22.93 (10.198)	-30.78 (10.198)	-4.33 (2.898)	-18.21 (2.162)	
95% CI [2]	-46.00, 0.14	-53.85, -7.71	-10.06, 1.39	-22.48, -13.94	
Difference (95% CI) in CFB [2]		-7.85 (-37.27, 21.57)		-13.88 (-20.20, -7.55)	
p-value [3]		0.561		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social life/Functioning

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	43.06 (25.408)	26.04 (22.367)	45.79 (26.194)	36.34 (25.794)	
Median	44.44	15.28	47.22	33.33	
Min, Max	13.9, 69.4	8.3, 69.4	0.0, 97.2	0.0, 100.0	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-17.77 (10.976)	-38.71 (10.976)	-4.94 (2.992)	-15.70 (2.247)	
95% CI [2]	-43.08, 7.54	-64.02, -13.40	-10.85, 0.96	-20.13, -11.26	
Difference (95% CI) in CFB [2]		-20.94 (-53.32, 11.44)		-10.75 (-17.18, -4.33)	
Hedges'G (95% CI) in CFB		-0.68 (-2.25, 0.56)		-0.46 (-0.79, -0.14)	
p-value [3]		0.174		0.001	
					0.521

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	47.92 (15.404)	58.75 (19.881)	49.05 (23.327)	48.77 (23.564)	
Median	54.17	56.25	45.83	50.00	
Min, Max	25.0, 58.3	37.5, 100.0	0.0, 100.0	0.0, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	34.38 (15.729)	40.83 (25.215)	41.79 (22.582)	38.35 (24.478)	
Median	37.50	33.33	41.67	33.33	
Min, Max	12.5, 50.0	16.7, 100.0	0.0, 91.7	0.0, 100.0	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	-13.97 (8.427)	-17.98 (8.427)	-6.22 (2.088)	-10.46 (1.598)	
95% CI [2]	-32.74, 4.81	-36.75, 0.80	-10.34, -2.10	-13.61, -7.30	
Difference (95% CI) in CFB [2]		-4.01 (-27.89, 19.88)		-4.23 (-8.79, 0.32)	
p-value [3]		0.716		0.068	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	118	
Mean (StdDev)	37.50 (24.767)	35.42 (25.250)	40.07 (23.107)	33.59 (22.461)	
Median	37.50	31.25	37.50	33.33	
Min, Max	8.3, 66.7	0.0, 95.8	0.0, 91.7	0.0, 95.8	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	-12.58 (11.344)	-24.92 (11.344)	-7.76 (2.282)	-14.84 (1.728)	
95% CI [2]	-37.85, 12.70	-50.20, 0.35	-12.26, -3.25	-18.25, -11.43	
Difference (95% CI) in CFB [2]		-12.34 (-44.49, 19.81)		-7.08 (-12.08, -2.08)	
p-value [3]		0.412		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	36.11 (24.414)	28.70 (16.724)	41.52 (24.129)	34.26 (24.993)	
Median	45.83	29.17	41.67	31.25	
Min, Max	8.3, 54.2	0.0, 58.3	0.0, 91.7	0.0, 95.8	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	-12.50 (15.238)	-25.00 (11.429)	-8.48 (2.686)	-17.02 (2.009)	
95% CI [2]	-47.64, 22.64	-51.35, 1.35	-13.78, -3.17	-20.99, -13.05	
Difference (95% CI) in CFB [2]		-12.50 (-52.76, 27.76)		-8.54 (-14.35, -2.74)	
p-value [3]		0.494		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	117	
Mean (StdDev)	38.54 (27.296)	21.88 (14.217)	38.47 (24.264)	31.34 (24.465)	
Median	43.75	25.00	37.50	25.00	
Min, Max	4.2, 62.5	0.0, 41.7	0.0, 95.8	0.0, 91.7	
C5D1 CFB					
n	4	8	58	111	
LS Mean (StdErr) [2]	-11.49 (13.059)	-28.79 (13.059)	-10.20 (2.738)	-18.71 (2.097)	
95% CI [2]	-41.60, 18.63	-58.91, 1.32	-15.61, -4.80	-22.85, -14.57	
Difference (95% CI) in CFB [2]		-17.31 (-55.83, 21.21)		-8.50 (-14.47, -2.54)	
p-value [3]		0.330		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	38.54 (24.621)	24.54 (13.412)	40.59 (24.921)	31.22 (24.865)	
Median	45.83	25.00	37.50	29.17	
Min, Max	4.2, 58.3	8.3, 45.8	0.0, 100.0	0.0, 95.8	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-9.65 (10.034)	-27.85 (10.034)	-7.73 (2.909)	-19.61 (2.170)	
95% CI [2]	-32.35, 13.05	-50.55, -5.15	-13.47, -1.98	-23.90, -15.33	
Difference (95% CI) in CFB [2]		-18.21 (-47.15, 10.74)		-11.89 (-18.23, -5.54)	
p-value [3]		0.188		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Emotions

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	38.54 (27.296)	16.15 (9.563)	37.86 (25.759)	31.62 (26.416)	
Median	39.58	20.83	33.33	25.00	
Min, Max	4.2, 70.8	0.0, 25.0	0.0, 100.0	0.0, 95.8	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-9.19 (10.674)	-38.03 (10.674)	-8.07 (3.010)	-15.58 (2.260)	
95% CI [2]	-33.80, 15.43	-62.65, -13.42	-14.02, -2.13	-20.04, -11.11	
Difference (95% CI) in CFB [2]		-28.85 (-60.33, 2.64)		-7.50 (-13.97, -1.04)	
Hedges'G (95% CI) in CFB		-0.96 (-2.65, 0.26)		-0.32 (-0.65, 0.00)	
p-value [3]		0.068		0.023	
					0.092

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	62.50 (14.434)	71.67 (26.701)	61.85 (23.184)	54.20 (21.550)	
Median	62.50	75.00	66.67	58.33	
Min, Max	50.0, 75.0	25.0, 100.0	0.0, 100.0	0.0, 100.0	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	64.58 (10.486)	43.33 (22.498)	52.82 (21.715)	40.22 (18.666)	
Median	66.67	45.83	50.00	41.67	
Min, Max	50.0, 75.0	0.0, 75.0	0.0, 91.7	0.0, 83.3	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	-0.66 (14.464)	-29.90 (14.464)	-6.64 (2.681)	-11.63 (2.052)	
95% CI [2]	-32.88, 31.57	-62.13, 2.33	-11.93, -1.35	-15.68, -7.58	
Difference (95% CI) in CFB [2]		-29.25 (-70.24, 11.75)		-4.99 (-10.84, 0.85)	
p-value [3]		0.143		0.094	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	118	
Mean (StdDev)	47.92 (18.478)	41.67 (22.567)	50.93 (22.852)	38.28 (19.709)	
Median	41.67	41.67	50.00	37.50	
Min, Max	33.3, 75.0	8.3, 83.3	0.0, 100.0	0.0, 91.7	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	-17.85 (16.120)	-32.15 (16.120)	-8.61 (3.186)	-13.46 (2.412)	
95% CI [2]	-53.76, 18.07	-68.07, 3.76	-14.90, -2.32	-18.23, -8.70	
Difference (95% CI) in CFB [2]		-14.31 (-60.00, 31.38)		-4.85 (-11.84, 2.13)	
p-value [3]		0.501		0.172	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	55.56 (26.788)	34.26 (21.018)	52.63 (23.367)	36.46 (20.386)	
Median	66.67	25.00	50.00	33.33	
Min, Max	25.0, 75.0	8.3, 66.7	0.0, 100.0	0.0, 100.0	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	-21.88 (19.080)	-35.94 (14.310)	-6.53 (3.354)	-16.23 (2.509)	
95% CI [2]	-65.87, 22.12	-68.94, -2.94	-13.15, 0.09	-21.18, -11.28	
Difference (95% CI) in CFB [2]		-14.06 (-64.47, 36.34)		-9.70 (-16.95, -2.45)	
p-value [3]		0.538		0.009	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	116	
Mean (StdDev)	52.08 (22.948)	32.29 (21.565)	51.67 (26.698)	36.71 (20.023)	
Median	54.17	29.17	54.17	33.33	
Min, Max	25.0, 75.0	8.3, 75.0	0.0, 100.0	0.0, 100.0	
C5D1 CFB					
n	4	8	58	110	
LS Mean (StdErr) [2]	-11.65 (16.476)	-32.80 (16.476)	-6.94 (3.292)	-15.14 (2.530)	
95% CI [2]	-49.64, 26.35	-70.79, 5.19	-13.44, -0.44	-20.14, -10.15	
Difference (95% CI) in CFB [2]		-21.15 (-69.76, 27.45)		-8.20 (-15.38, -1.02)	
p-value [3]		0.345		0.025	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	56.25 (23.936)	37.04 (23.976)	50.29 (25.071)	37.36 (22.532)	
Median	62.50	33.33	50.00	33.33	
Min, Max	25.0, 75.0	8.3, 66.7	0.0, 100.0	0.0, 91.7	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-3.77 (19.045)	-26.78 (19.045)	-8.01 (3.336)	-14.99 (2.489)	
95% CI [2]	-46.86, 39.31	-69.86, 16.30	-14.59, -1.42	-19.91, -10.08	
Difference (95% CI) in CFB [2]		-23.01 (-77.94, 31.92)		-6.99 (-14.27, 0.29)	
p-value [3]		0.368		0.060	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.8.1.8a
Change from Baseline in MC-QoL by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Skin

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	50.00 (24.533)	25.00 (8.909)	51.72 (24.719)	36.97 (21.498)	
Median	50.00	25.00	50.00	33.33	
Min, Max	25.0, 75.0	8.3, 33.3	0.0, 100.0	0.0, 91.7	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-11.54 (10.847)	-38.46 (10.847)	-6.00 (3.438)	-14.26 (2.582)	
95% CI [2]	-36.55, 13.47	-63.47, -13.45	-12.79, 0.79	-19.36, -9.16	
Difference (95% CI) in CFB [2]		-26.92 (-58.92, 5.07)		-8.26 (-15.64, -0.88)	
Hedges'G (95% CI) in CFB		-0.88 (-2.54, 0.34)		-0.31 (-0.63, 0.01)	
p-value [3]		0.088		0.029	
					0.119

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-sum-g-itt-thpy-a.sas Date: 15:52/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	2.7 (1.17)	2.3 (1.12)	2.8 (1.17)	2.9 (1.17)	
Median	3.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	1, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	2.2 (1.02)	1.6 (0.96)	2.5 (1.21)	1.7 (0.87)	
Median	2.0	2.0	3.0	1.0	
Min, Max	0, 4	0, 4	0, 4	1, 3	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	-0.37 (0.156)	-0.58 (0.112)	-0.70 (0.483)	-1.73 (0.612)	
95% CI [2]	-0.68, -0.06	-0.80, -0.36	-1.72, 0.33	-3.03, -0.43	
Difference (95% CI) in CFB [2]		-0.21 (-0.55, 0.13)		-1.03 (-1.99, -0.08)	
p-value [3]		0.223		0.036	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	119	10	9	
Mean (StdDev)	2.1 (1.14)	1.5 (0.96)	2.0 (1.15)	1.7 (1.12)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-0.54 (0.171)	-0.66 (0.122)	-0.89 (0.662)	-1.56 (0.834)	
95% CI [2]	-0.88, -0.21	-0.91, -0.42	-2.30, 0.52	-3.33, 0.22	
Difference (95% CI) in CFB [2]		-0.12 (-0.49, 0.25)		-0.67 (-1.99, 0.66)	
p-value [3]		0.528		0.300	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	2.1 (1.07)	1.4 (1.03)	2.6 (1.27)	1.2 (0.83)	
Median	2.0	1.0	3.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 3	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-0.51 (0.185)	-0.85 (0.132)	-0.53 (0.658)	-2.37 (0.877)	
95% CI [2]	-0.87, -0.14	-1.11, -0.59	-1.96, 0.90	-4.28, -0.46	
Difference (95% CI) in CFB [2]		-0.34 (-0.73, 0.06)		-1.84 (-3.44, -0.24)	
p-value [3]		0.093		0.027	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	116	9	8	
Mean (StdDev)	2.1 (1.12)	1.3 (1.01)	2.9 (1.45)	1.3 (0.71)	
Median	2.0	1.0	4.0	1.0	
Min, Max	0, 4	0, 4	1, 4	1, 3	
C5D1 CFB					
n	53	110	9	8	
LS Mean (StdErr) [2]	-0.48 (0.184)	-0.83 (0.135)	-0.70 (0.591)	-2.85 (0.765)	
95% CI [2]	-0.84, -0.11	-1.10, -0.57	-1.97, 0.58	-4.50, -1.20	
Difference (95% CI) in CFB [2]		-0.36 (-0.76, 0.04)		-2.15 (-3.44, -0.86)	
p-value [3]		0.081		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	2.1 (1.17)	1.5 (1.04)	2.5 (1.51)	1.6 (1.24)	
Median	2.0	1.0	2.5	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-0.58 (0.180)	-0.74 (0.128)	-0.40 (0.735)	-1.67 (0.989)	
95% CI [2]	-0.93, -0.22	-1.00, -0.49	-1.99, 1.19	-3.80, 0.47	
Difference (95% CI) in CFB [2]		-0.17 (-0.56, 0.22)		-1.27 (-3.02, 0.48)	
p-value [3]		0.403		0.142	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	2.1 (1.17)	1.3 (0.99)	2.9 (0.99)	1.6 (1.19)	
Median	2.0	1.0	3.0	1.0	
Min, Max	0, 4	0, 4	1, 4	1, 4	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-0.46 (0.174)	-0.79 (0.123)	-0.25 (0.623)	-1.75 (0.824)	
95% CI [2]	-0.80, -0.12	-1.04, -0.55	-1.59, 1.09	-3.52, 0.02	
Difference (95% CI) in CFB [2]		-0.33 (-0.71, 0.04)		-1.50 (-2.84, -0.16)	
Hedges'G (95% CI) in CFB		-0.26 (-0.60, 0.07)		-0.67 (-1.81, 0.27)	
p-value [3]		0.078		0.030	
					0.076

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	2.4 (1.17)	2.1 (1.12)	3.0 (1.00)	2.0 (1.58)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	2.0 (1.15)	1.4 (0.98)	2.8 (0.98)	1.2 (0.97)	
Median	2.0	1.0	3.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 3	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	-0.17 (0.168)	-0.52 (0.121)	-0.62 (0.487)	-1.48 (0.617)	
95% CI [2]	-0.51, 0.16	-0.76, -0.28	-1.65, 0.41	-2.78, -0.17	
Difference (95% CI) in CFB [2]		-0.35 (-0.71, 0.02)		-0.85 (-1.82, 0.11)	
p-value [3]		0.064		0.078	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	119	10	9	
Mean (StdDev)	2.0 (1.26)	1.4 (0.99)	2.4 (1.07)	1.3 (1.22)	
Median	2.0	1.0	3.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-0.27 (0.181)	-0.60 (0.130)	-1.28 (0.643)	-1.61 (0.810)	
95% CI [2]	-0.63, 0.09	-0.85, -0.34	-2.65, 0.09	-3.34, 0.11	
Difference (95% CI) in CFB [2]		-0.33 (-0.72, 0.07)		-0.33 (-1.62, 0.95)	
p-value [3]		0.105		0.588	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	2.1 (1.12)	1.3 (1.02)	2.4 (1.13)	1.1 (1.05)	
Median	2.0	1.0	3.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 3	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-0.12 (0.183)	-0.68 (0.130)	-0.75 (0.551)	-1.10 (0.734)	
95% CI [2]	-0.48, 0.24	-0.94, -0.42	-1.95, 0.46	-2.70, 0.50	
Difference (95% CI) in CFB [2]		-0.56 (-0.95, -0.17)		-0.36 (-1.70, 0.98)	
p-value [3]		0.005		0.569	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	116	9	8	
Mean (StdDev)	1.9 (1.26)	1.4 (0.99)	2.8 (1.30)	1.1 (1.13)	
Median	2.0	1.0	3.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 3	
C5D1 CFB					
n	53	110	9	8	
LS Mean (StdErr) [2]	-0.23 (0.186)	-0.59 (0.136)	-0.61 (0.632)	-1.27 (0.820)	
95% CI [2]	-0.59, 0.14	-0.86, -0.32	-1.98, 0.75	-3.04, 0.50	
Difference (95% CI) in CFB [2]		-0.36 (-0.77, 0.04)		-0.65 (-2.03, 0.73)	
p-value [3]		0.076		0.326	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	2.0 (1.17)	1.5 (1.06)	2.6 (1.30)	0.6 (0.88)	
Median	2.0	1.0	2.5	0.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-0.14 (0.185)	-0.54 (0.132)	-0.59 (0.490)	-2.04 (0.659)	
95% CI [2]	-0.50, 0.23	-0.80, -0.28	-1.65, 0.47	-3.47, -0.62	
Difference (95% CI) in CFB [2]		-0.41 (-0.81, -0.01)		-1.45 (-2.62, -0.28)	
p-value [3]		0.046		0.019	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	1.9 (1.20)	1.4 (1.11)	3.0 (0.94)	1.1 (0.99)	
Median	2.0	1.0	3.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 3	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-0.16 (0.195)	-0.51 (0.138)	-0.46 (0.566)	-1.75 (0.749)	
95% CI [2]	-0.55, 0.22	-0.79, -0.24	-1.68, 0.75	-3.36, -0.14	
Difference (95% CI) in CFB [2]		-0.35 (-0.77, 0.06)		-1.29 (-2.50, -0.07)	
Hedges'G (95% CI) in CFB		-0.25 (-0.59, 0.09)		-0.63 (-1.76, 0.31)	
p-value [3]		0.096		0.040	
					0.350

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	2.3 (1.16)	2.3 (1.08)	2.2 (0.98)	1.7 (1.22)	
Median	2.0	2.0	3.0	1.0	
Min, Max	0, 4	0, 4	1, 3	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	2.1 (1.10)	1.9 (1.04)	1.7 (0.90)	1.1 (1.17)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 3	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	-0.11 (0.153)	-0.36 (0.110)	-0.21 (0.277)	-0.16 (0.352)	
95% CI [2]	-0.41, 0.19	-0.58, -0.15	-0.80, 0.38	-0.90, 0.59	
Difference (95% CI) in CFB [2]		-0.25 (-0.58, 0.08)		0.05 (-0.50, 0.60)	
p-value [3]		0.135		0.853	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	119	10	9	
Mean (StdDev)	2.1 (1.00)	1.8 (1.12)	1.4 (0.84)	1.4 (0.88)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 3	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-0.05 (0.170)	-0.47 (0.122)	-0.33 (0.490)	0.33 (0.617)	
95% CI [2]	-0.39, 0.29	-0.71, -0.23	-1.38, 0.71	-0.98, 1.65	
Difference (95% CI) in CFB [2]		-0.43 (-0.80, -0.05)		0.67 (-0.31, 1.65)	
p-value [3]		0.025		0.167	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	2.1 (1.15)	1.7 (1.02)	1.7 (0.76)	1.3 (1.00)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	1, 3	0, 3	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-0.14 (0.179)	-0.58 (0.127)	-0.12 (0.593)	0.18 (0.791)	
95% CI [2]	-0.50, 0.21	-0.83, -0.33	-1.41, 1.17	-1.55, 1.90	
Difference (95% CI) in CFB [2]		-0.43 (-0.82, -0.05)		0.29 (-1.15, 1.74)	
p-value [3]		0.026		0.665	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	116	9	8	
Mean (StdDev)	2.0 (1.25)	1.7 (1.06)	2.0 (1.22)	1.3 (0.71)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	1, 4	1, 3	
C5D1 CFB					
n	53	110	9	8	
LS Mean (StdErr) [2]	-0.25 (0.189)	-0.53 (0.138)	0.05 (0.308)	0.08 (0.399)	
95% CI [2]	-0.62, 0.12	-0.80, -0.26	-0.61, 0.72	-0.78, 0.94	
Difference (95% CI) in CFB [2]		-0.28 (-0.69, 0.13)		0.03 (-0.64, 0.70)	
p-value [3]		0.180		0.930	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	1.9 (1.16)	1.7 (1.13)	1.5 (1.20)	1.2 (0.67)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-0.21 (0.179)	-0.58 (0.128)	-0.19 (0.625)	-0.04 (0.841)	
95% CI [2]	-0.56, 0.15	-0.83, -0.32	-1.54, 1.16	-1.86, 1.78	
Difference (95% CI) in CFB [2]		-0.37 (-0.76, 0.02)		0.15 (-1.34, 1.64)	
p-value [3]		0.062		0.831	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	1.9 (1.11)	1.7 (1.10)	1.9 (1.29)	1.0 (0.76)	
Median	2.0	2.0	1.5	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-0.26 (0.199)	-0.58 (0.141)	-0.10 (0.563)	-0.33 (0.745)	
95% CI [2]	-0.66, 0.13	-0.85, -0.30	-1.30, 1.11	-1.93, 1.26	
Difference (95% CI) in CFB [2]		-0.31 (-0.74, 0.11)		-0.24 (-1.45, 0.97)	
Hedges'G (95% CI) in CFB		-0.21 (-0.55, 0.12)		-0.12 (-1.14, 0.87)	
p-value [3]		0.148		0.679	
					0.813

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	2.2 (1.20)	2.2 (1.22)	1.5 (1.13)	1.7 (1.22)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	127	11	9	
Mean (StdDev)	1.8 (1.20)	1.5 (1.10)	1.3 (1.01)	1.4 (1.13)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 3	
C2D1 CFB					
n	55	122	11	9	
LS Mean (StdErr) [2]	-0.32 (0.172)	-0.59 (0.125)	-0.54 (0.427)	-0.63 (0.542)	
95% CI [2]	-0.66, 0.02	-0.84, -0.35	-1.44, 0.37	-1.78, 0.52	
Difference (95% CI) in CFB [2]		-0.28 (-0.65, 0.09)		-0.09 (-0.93, 0.76)	
p-value [3]		0.142		0.825	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	119	10	9	
Mean (StdDev)	1.8 (1.32)	1.5 (1.15)	1.1 (0.99)	0.9 (0.78)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-0.23 (0.193)	-0.59 (0.138)	-0.56 (0.400)	-1.22 (0.504)	
95% CI [2]	-0.61, 0.15	-0.86, -0.31	-1.41, 0.30	-2.30, -0.15	
Difference (95% CI) in CFB [2]		-0.36 (-0.78, 0.06)		-0.67 (-1.47, 0.13)	
p-value [3]		0.096		0.096	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	1.8 (1.23)	1.5 (1.19)	1.0 (0.82)	1.0 (0.87)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 2	0, 2	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-0.35 (0.186)	-0.63 (0.132)	-0.59 (0.603)	-1.12 (0.804)	
95% CI [2]	-0.72, 0.02	-0.89, -0.37	-1.90, 0.73	-2.87, 0.63	
Difference (95% CI) in CFB [2]		-0.28 (-0.68, 0.11)		-0.53 (-1.99, 0.94)	
p-value [3]		0.161		0.446	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	116	9	8	
Mean (StdDev)	1.8 (1.08)	1.4 (1.16)	1.4 (1.24)	0.9 (0.99)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C5D1 CFB					
n	53	110	9	8	
LS Mean (StdErr) [2]	-0.24 (0.183)	-0.71 (0.134)	-0.28 (0.800)	-1.29 (1.037)	
95% CI [2]	-0.60, 0.12	-0.97, -0.44	-2.00, 1.45	-3.53, 0.95	
Difference (95% CI) in CFB [2]		-0.47 (-0.87, -0.07)		-1.01 (-2.76, 0.73)	
p-value [3]		0.020		0.231	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	1.8 (1.21)	1.3 (1.13)	1.1 (0.83)	0.9 (0.93)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 2	0, 3	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-0.18 (0.184)	-0.66 (0.131)	-0.52 (0.740)	-0.75 (0.995)	
95% CI [2]	-0.54, 0.18	-0.92, -0.40	-2.11, 1.08	-2.90, 1.40	
Difference (95% CI) in CFB [2]		-0.48 (-0.88, -0.08)		-0.23 (-2.00, 1.53)	
p-value [3]		0.019		0.779	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	1.8 (1.13)	1.4 (1.23)	1.2 (0.79)	1.1 (0.83)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 2	0, 3	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-0.13 (0.192)	-0.52 (0.136)	-0.52 (0.524)	-1.33 (0.693)	
95% CI [2]	-0.51, 0.25	-0.79, -0.26	-1.65, 0.60	-2.82, 0.15	
Difference (95% CI) in CFB [2]		-0.40 (-0.81, 0.01)		-0.81 (-1.93, 0.31)	
Hedges'G (95% CI) in CFB		-0.28 (-0.62, 0.05)		-0.43 (-1.51, 0.53)	
p-value [3]		0.058		0.144	
					0.922

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	3.2 (0.89)	3.2 (0.90)	2.7 (0.90)	2.4 (1.13)	
Median	3.0	3.0	3.0	2.0	
Min, Max	1, 4	1, 4	1, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	2.8 (0.99)	2.7 (1.07)	2.5 (0.69)	2.1 (1.05)	
Median	3.0	3.0	2.0	2.0	
Min, Max	1, 4	0, 4	2, 4	1, 4	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	-0.36 (0.143)	-0.51 (0.103)	-0.60 (0.386)	-0.95 (0.489)	
95% CI [2]	-0.64, -0.08	-0.71, -0.30	-1.42, 0.22	-1.98, 0.09	
Difference (95% CI) in CFB [2]		-0.15 (-0.46, 0.16)		-0.35 (-1.11, 0.41)	
p-value [3]		0.355		0.346	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	119	10	9	
Mean (StdDev)	2.8 (1.06)	2.5 (1.07)	2.1 (1.10)	1.9 (1.27)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-0.45 (0.165)	-0.70 (0.118)	-0.75 (0.484)	-0.92 (0.609)	
95% CI [2]	-0.77, -0.12	-0.93, -0.47	-1.78, 0.28	-2.22, 0.38	
Difference (95% CI) in CFB [2]		-0.25 (-0.61, 0.11)		-0.17 (-1.13, 0.80)	
p-value [3]		0.164		0.718	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	2.8 (1.09)	2.5 (1.10)	2.7 (1.38)	1.3 (0.87)	
Median	3.0	3.0	3.0	2.0	
Min, Max	1, 4	0, 4	1, 4	0, 2	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-0.50 (0.170)	-0.64 (0.121)	0.01 (0.811)	-1.04 (1.082)	
95% CI [2]	-0.84, -0.16	-0.88, -0.40	-1.76, 1.78	-3.40, 1.31	
Difference (95% CI) in CFB [2]		-0.14 (-0.51, 0.22)		-1.05 (-3.02, 0.92)	
p-value [3]		0.435		0.268	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	116	9	8	
Mean (StdDev)	2.6 (1.22)	2.4 (1.12)	3.0 (1.00)	1.3 (0.71)	
Median	3.0	2.0	3.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C5D1 CFB					
n	53	110	9	8	
LS Mean (StdErr) [2]	-0.63 (0.172)	-0.76 (0.126)	0.28 (0.621)	-1.07 (0.805)	
95% CI [2]	-0.97, -0.29	-1.01, -0.51	-1.06, 1.62	-2.81, 0.67	
Difference (95% CI) in CFB [2]		-0.13 (-0.50, 0.24)		-1.35 (-2.70, 0.01)	
p-value [3]		0.489		0.051	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	2.6 (1.09)	2.3 (1.15)	2.5 (1.20)	1.4 (0.88)	
Median	3.0	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-0.66 (0.175)	-0.83 (0.124)	-0.93 (0.679)	-1.37 (0.914)	
95% CI [2]	-1.01, -0.32	-1.08, -0.58	-2.39, 0.54	-3.35, 0.60	
Difference (95% CI) in CFB [2]		-0.17 (-0.55, 0.21)		-0.45 (-2.07, 1.17)	
p-value [3]		0.380		0.558	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	2.6 (1.11)	2.4 (1.07)	2.6 (0.97)	1.8 (0.89)	
Median	3.0	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 3	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-0.68 (0.170)	-0.74 (0.120)	-0.35 (0.815)	-1.08 (1.078)	
95% CI [2]	-1.02, -0.35	-0.98, -0.50	-2.09, 1.40	-3.39, 1.23	
Difference (95% CI) in CFB [2]		-0.06 (-0.42, 0.31)		-0.74 (-2.49, 1.01)	
Hedges'G (95% CI) in CFB		-0.05 (-0.38, 0.29)		-0.25 (-1.30, 0.72)	
p-value [3]		0.754		0.380	
					0.186

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	2.3 (1.07)	2.1 (1.13)	1.2 (0.87)	1.8 (1.09)	
Median	2.0	2.0	1.0	2.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	2.1 (1.06)	1.8 (1.04)	1.1 (0.70)	1.4 (0.88)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 2	0, 3	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	-0.16 (0.144)	-0.29 (0.104)	-0.06 (0.347)	-0.32 (0.440)	
95% CI [2]	-0.45, 0.12	-0.50, -0.09	-0.80, 0.68	-1.25, 0.61	
Difference (95% CI) in CFB [2]		-0.13 (-0.44, 0.19)		-0.26 (-0.95, 0.43)	
p-value [3]		0.425		0.433	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	119	10	9	
Mean (StdDev)	2.0 (1.05)	1.6 (0.99)	1.0 (0.94)	1.2 (1.09)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 3	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-0.28 (0.169)	-0.50 (0.121)	-0.12 (0.290)	-0.71 (0.365)	
95% CI [2]	-0.61, 0.06	-0.74, -0.26	-0.74, 0.49	-1.49, 0.07	
Difference (95% CI) in CFB [2]		-0.22 (-0.59, 0.15)		-0.58 (-1.16, -0.01)	
p-value [3]		0.242		0.048	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	1.9 (1.18)	1.7 (1.16)	1.4 (1.27)	1.3 (0.87)	
Median	2.0	2.0	1.0	2.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-0.30 (0.177)	-0.39 (0.125)	0.83 (0.322)	0.06 (0.429)	
95% CI [2]	-0.65, 0.05	-0.63, -0.14	0.13, 1.53	-0.88, 0.99	
Difference (95% CI) in CFB [2]		-0.08 (-0.46, 0.29)		-0.78 (-1.56, 0.00)	
p-value [3]		0.660		0.051	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	116	9	8	
Mean (StdDev)	2.0 (1.22)	1.7 (1.13)	1.4 (1.33)	1.0 (1.20)	
Median	2.0	2.0	1.0	0.5	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C5D1 CFB					
n	53	110	9	8	
LS Mean (StdErr) [2]	-0.39 (0.162)	-0.35 (0.118)	0.19 (0.542)	-0.94 (0.703)	
95% CI [2]	-0.71, -0.07	-0.59, -0.12	-0.98, 1.36	-2.46, 0.58	
Difference (95% CI) in CFB [2]		0.03 (-0.32, 0.38)		-1.13 (-2.31, 0.06)	
p-value [3]		0.862		0.061	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	1.9 (1.07)	1.6 (1.13)	1.1 (0.99)	0.8 (0.83)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-0.35 (0.163)	-0.42 (0.116)	0.00 (0.421)	-1.00 (0.566)	
95% CI [2]	-0.67, -0.02	-0.65, -0.19	-0.91, 0.91	-2.22, 0.22	
Difference (95% CI) in CFB [2]		-0.07 (-0.43, 0.28)		-1.00 (-2.00, 0.00)	
p-value [3]		0.686		0.051	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	1.9 (1.06)	1.6 (1.10)	1.1 (1.10)	0.6 (0.74)	
Median	2.0	1.0	1.0	0.5	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-0.40 (0.176)	-0.38 (0.124)	-0.11 (0.389)	-1.25 (0.515)	
95% CI [2]	-0.75, -0.05	-0.62, -0.13	-0.94, 0.73	-2.35, -0.15	
Difference (95% CI) in CFB [2]		0.02 (-0.35, 0.40)		-1.14 (-1.98, -0.31)	
Hedges'G (95% CI) in CFB		0.02 (-0.32, 0.35)		-0.82 (-1.99, 0.12)	
p-value [3]		0.909		0.011	
					0.126

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	2.8 (1.10)	2.7 (1.21)	2.0 (1.18)	2.6 (1.33)	
Median	3.0	3.0	2.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	127	11	9	
Mean (StdDev)	2.4 (1.09)	2.2 (1.15)	1.9 (0.94)	1.9 (1.05)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 3	0, 3	
C2D1 CFB					
n	55	122	11	9	
LS Mean (StdErr) [2]	-0.33 (0.143)	-0.41 (0.104)	-0.39 (0.319)	-0.79 (0.405)	
95% CI [2]	-0.61, -0.05	-0.62, -0.21	-1.07, 0.29	-1.65, 0.07	
Difference (95% CI) in CFB [2]		-0.08 (-0.39, 0.23)		-0.40 (-1.03, 0.23)	
p-value [3]		0.609		0.199	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	119	10	9	
Mean (StdDev)	2.3 (1.13)	2.1 (1.23)	1.8 (1.03)	1.8 (1.20)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-0.56 (0.174)	-0.60 (0.124)	-0.39 (0.350)	-0.72 (0.440)	
95% CI [2]	-0.91, -0.22	-0.84, -0.35	-1.13, 0.36	-1.66, 0.22	
Difference (95% CI) in CFB [2]		-0.03 (-0.41, 0.35)		-0.33 (-1.03, 0.37)	
p-value [3]		0.867		0.325	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	2.5 (1.15)	2.2 (1.23)	2.0 (0.82)	1.7 (1.00)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 3	0, 3	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-0.37 (0.184)	-0.55 (0.131)	0.23 (0.616)	0.02 (0.821)	
95% CI [2]	-0.74, -0.01	-0.81, -0.29	-1.12, 1.57	-1.77, 1.81	
Difference (95% CI) in CFB [2]		-0.18 (-0.57, 0.22)		-0.20 (-1.70, 1.29)	
p-value [3]		0.376		0.773	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	116	9	8	
Mean (StdDev)	2.5 (1.09)	2.2 (1.22)	2.0 (1.22)	1.5 (1.20)	
Median	3.0	2.0	2.0	1.5	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C5D1 CFB					
n	53	110	9	8	
LS Mean (StdErr) [2]	-0.34 (0.168)	-0.53 (0.123)	0.11 (0.541)	-0.56 (0.702)	
95% CI [2]	-0.68, -0.01	-0.77, -0.29	-1.06, 1.28	-2.07, 0.96	
Difference (95% CI) in CFB [2]		-0.19 (-0.55, 0.18)		-0.67 (-1.85, 0.51)	
p-value [3]		0.308		0.245	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	2.6 (1.16)	2.1 (1.20)	1.6 (1.06)	1.7 (1.32)	
Median	3.0	2.0	1.5	2.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-0.23 (0.177)	-0.56 (0.126)	-0.53 (0.624)	-0.33 (0.840)	
95% CI [2]	-0.58, 0.12	-0.81, -0.31	-1.88, 0.81	-2.15, 1.48	
Difference (95% CI) in CFB [2]		-0.34 (-0.72, 0.05)		0.20 (-1.29, 1.69)	
p-value [3]		0.086		0.776	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	2.3 (1.16)	2.2 (1.17)	2.0 (1.25)	1.4 (1.30)	
Median	2.0	2.0	2.5	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-0.44 (0.171)	-0.41 (0.121)	-0.35 (0.563)	-1.58 (0.745)	
95% CI [2]	-0.78, -0.10	-0.65, -0.17	-1.55, 0.86	-3.18, 0.01	
Difference (95% CI) in CFB [2]		0.03 (-0.34, 0.39)		-1.24 (-2.45, -0.03)	
Hedges'G (95% CI) in CFB		0.02 (-0.31, 0.36)		-0.61 (-1.73, 0.33)	
p-value [3]		0.877		0.045	
					0.032

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	2.4 (1.11)	2.6 (1.09)	1.5 (0.93)	2.1 (1.17)	
Median	2.0	3.0	2.0	3.0	
Min, Max	0, 4	0, 4	0, 3	0, 3	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	57	128	11	9	
Mean (StdDev)	2.2 (1.15)	2.1 (1.11)	1.5 (1.29)	1.3 (1.22)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	54	123	11	9	
LS Mean (StdErr) [2]	-0.14 (0.132)	-0.49 (0.095)	0.04 (0.568)	-0.87 (0.721)	
95% CI [2]	-0.40, 0.12	-0.68, -0.30	-1.17, 1.24	-2.40, 0.65	
Difference (95% CI) in CFB [2]		-0.35 (-0.64, -0.06)		-0.91 (-2.03, 0.21)	
p-value [3]		0.017		0.105	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	119	10	9	
Mean (StdDev)	2.2 (1.22)	1.9 (1.15)	1.4 (0.97)	1.4 (0.88)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 3	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-0.18 (0.134)	-0.65 (0.096)	0.43 (0.410)	-0.15 (0.516)	
95% CI [2]	-0.44, 0.09	-0.84, -0.46	-0.44, 1.30	-1.25, 0.95	
Difference (95% CI) in CFB [2]		-0.47 (-0.76, -0.18)		-0.58 (-1.40, 0.24)	
p-value [3]		0.002		0.150	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	2.0 (1.24)	2.0 (1.16)	1.6 (0.79)	1.3 (1.00)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	1, 3	0, 3	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-0.24 (0.154)	-0.59 (0.109)	0.45 (0.401)	-0.62 (0.535)	
95% CI [2]	-0.54, 0.07	-0.80, -0.37	-0.42, 1.33	-1.79, 0.55	
Difference (95% CI) in CFB [2]		-0.35 (-0.68, -0.02)		-1.07 (-2.05, -0.10)	
p-value [3]		0.038		0.034	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	116	9	8	
Mean (StdDev)	2.1 (1.25)	1.9 (1.16)	2.1 (1.17)	1.3 (0.71)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C5D1 CFB					
n	53	110	9	8	
LS Mean (StdErr) [2]	-0.28 (0.158)	-0.64 (0.115)	0.76 (0.406)	-0.46 (0.526)	
95% CI [2]	-0.60, 0.03	-0.87, -0.42	-0.12, 1.64	-1.60, 0.67	
Difference (95% CI) in CFB [2]		-0.36 (-0.70, -0.02)		-1.22 (-2.11, -0.34)	
p-value [3]		0.039		0.011	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	2.0 (1.25)	1.8 (1.22)	1.6 (1.06)	1.4 (1.13)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-0.32 (0.161)	-0.77 (0.115)	0.43 (0.533)	-0.12 (0.718)	
95% CI [2]	-0.64, -0.00	-0.99, -0.54	-0.73, 1.58	-1.68, 1.43	
Difference (95% CI) in CFB [2]		-0.45 (-0.80, -0.10)		-0.55 (-1.82, 0.72)	
p-value [3]		0.012		0.367	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	2.1 (1.22)	1.8 (1.23)	1.3 (0.82)	1.3 (0.71)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-0.17 (0.164)	-0.76 (0.116)	0.40 (0.441)	-0.33 (0.583)	
95% CI [2]	-0.49, 0.16	-0.99, -0.53	-0.54, 1.35	-1.58, 0.92	
Difference (95% CI) in CFB [2]		-0.60 (-0.95, -0.24)		-0.74 (-1.68, 0.21)	
Hedges'G (95% CI) in CFB		-0.49 (-0.84, -0.16)		-0.47 (-1.56, 0.49)	
p-value [3]		0.001		0.116	
					0.670

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	2.1 (1.36)	2.2 (1.40)	1.4 (1.36)	0.7 (0.87)	
Median	2.0	2.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	1.8 (1.38)	1.6 (1.34)	0.7 (1.01)	0.7 (1.12)	
Median	2.0	2.0	0.0	0.0	
Min, Max	0, 4	0, 4	0, 3	0, 3	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	-0.19 (0.206)	-0.46 (0.149)	-0.43 (0.546)	0.09 (0.693)	
95% CI [2]	-0.60, 0.21	-0.75, -0.17	-1.58, 0.73	-1.38, 1.55	
Difference (95% CI) in CFB [2]		-0.27 (-0.71, 0.18)		0.51 (-0.57, 1.59)	
p-value [3]		0.241		0.330	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	118	10	9	
Mean (StdDev)	1.9 (1.30)	1.6 (1.32)	0.9 (1.20)	0.2 (0.67)	
Median	2.0	1.0	0.5	0.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-0.20 (0.221)	-0.49 (0.158)	-0.15 (0.481)	-0.24 (0.606)	
95% CI [2]	-0.63, 0.24	-0.80, -0.18	-1.18, 0.87	-1.53, 1.06	
Difference (95% CI) in CFB [2]		-0.29 (-0.77, 0.19)		-0.08 (-1.04, 0.88)	
p-value [3]		0.229		0.856	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	1.9 (1.19)	1.5 (1.30)	1.1 (1.46)	0.8 (0.97)	
Median	2.0	1.0	0.0	0.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-0.11 (0.230)	-0.60 (0.163)	-0.07 (0.534)	0.30 (0.712)	
95% CI [2]	-0.56, 0.35	-0.92, -0.28	-1.23, 1.09	-1.25, 1.85	
Difference (95% CI) in CFB [2]		-0.50 (-0.99, -0.01)		0.37 (-0.93, 1.66)	
p-value [3]		0.047		0.550	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	54	117	9	8	
Mean (StdDev)	1.9 (1.21)	1.4 (1.29)	1.4 (1.33)	0.5 (0.76)	
Median	2.0	1.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C5D1 CFB					
n	52	111	9	8	
LS Mean (StdErr) [2]	-0.18 (0.216)	-0.79 (0.157)	0.09 (0.657)	-0.09 (0.852)	
95% CI [2]	-0.60, 0.25	-1.10, -0.48	-1.33, 1.51	-1.93, 1.75	
Difference (95% CI) in CFB [2]		-0.61 (-1.08, -0.14)		-0.18 (-1.61, 1.25)	
p-value [3]		0.011		0.790	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	2.0 (1.30)	1.5 (1.30)	1.1 (1.13)	0.6 (0.88)	
Median	2.0	1.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-0.12 (0.216)	-0.65 (0.154)	-0.14 (0.563)	0.04 (0.757)	
95% CI [2]	-0.55, 0.31	-0.96, -0.35	-1.36, 1.07	-1.59, 1.68	
Difference (95% CI) in CFB [2]		-0.53 (-1.00, -0.06)		0.18 (-1.16, 1.52)	
p-value [3]		0.026		0.772	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	1.8 (1.31)	1.4 (1.29)	0.9 (1.10)	0.5 (0.76)	
Median	2.0	1.0	0.5	0.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-0.22 (0.220)	-0.65 (0.155)	0.29 (0.445)	0.50 (0.589)	
95% CI [2]	-0.65, 0.21	-0.96, -0.35	-0.67, 1.24	-0.76, 1.76	
Difference (95% CI) in CFB [2]		-0.43 (-0.90, 0.04)		0.21 (-0.74, 1.17)	
Hedges'G (95% CI) in CFB		-0.27 (-0.61, 0.07)		0.13 (-0.85, 1.16)	
p-value [3]		0.072		0.638	
					0.398

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	2.7 (1.20)	2.6 (1.30)	1.6 (1.21)	2.6 (1.24)	
Median	3.0	3.0	2.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	2.4 (1.17)	2.1 (1.31)	1.6 (1.36)	1.2 (1.09)	
Median	2.5	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	-0.28 (0.171)	-0.48 (0.123)	0.40 (0.468)	-0.95 (0.593)	
95% CI [2]	-0.62, 0.05	-0.73, -0.24	-0.59, 1.39	-2.21, 0.31	
Difference (95% CI) in CFB [2]		-0.20 (-0.57, 0.17)		-1.35 (-2.27, -0.42)	
p-value [3]		0.285		0.007	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	118	10	9	
Mean (StdDev)	2.4 (1.18)	1.9 (1.30)	1.5 (1.18)	0.9 (0.93)	
Median	3.0	2.0	1.5	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-0.32 (0.178)	-0.66 (0.127)	-0.36 (0.466)	-2.19 (0.587)	
95% CI [2]	-0.67, 0.03	-0.91, -0.41	-1.35, 0.63	-3.45, -0.94	
Difference (95% CI) in CFB [2]		-0.33 (-0.72, 0.05)		-1.83 (-2.76, -0.90)	
p-value [3]		0.091		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	2.2 (1.28)	2.0 (1.36)	1.6 (1.62)	1.4 (1.13)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-0.43 (0.195)	-0.63 (0.139)	0.07 (0.619)	-1.30 (0.825)	
95% CI [2]	-0.82, -0.05	-0.90, -0.35	-1.28, 1.42	-3.10, 0.50	
Difference (95% CI) in CFB [2]		-0.19 (-0.61, 0.22)		-1.37 (-2.87, 0.14)	
p-value [3]		0.358		0.071	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	54	117	9	8	
Mean (StdDev)	2.2 (1.20)	1.8 (1.24)	1.8 (1.30)	0.8 (0.89)	
Median	2.0	2.0	1.0	0.5	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C5D1 CFB					
n	52	111	9	8	
LS Mean (StdErr) [2]	-0.44 (0.180)	-0.83 (0.131)	-0.19 (0.813)	-2.38 (1.054)	
95% CI [2]	-0.79, -0.08	-1.09, -0.57	-1.95, 1.57	-4.66, -0.11	
Difference (95% CI) in CFB [2]		-0.39 (-0.78, -0.00)		-2.19 (-3.97, -0.42)	
p-value [3]		0.048		0.019	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	2.4 (1.28)	1.8 (1.30)	1.6 (1.06)	0.8 (0.83)	
Median	2.5	2.0	1.5	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-0.20 (0.188)	-0.75 (0.134)	0.11 (0.549)	-1.54 (0.740)	
95% CI [2]	-0.57, 0.17	-1.01, -0.49	-1.08, 1.30	-3.14, 0.06	
Difference (95% CI) in CFB [2]		-0.55 (-0.96, -0.15)		-1.65 (-2.96, -0.34)	
p-value [3]		0.008		0.017	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	2.2 (1.28)	1.8 (1.36)	1.8 (1.32)	1.3 (0.89)	
Median	2.0	2.0	2.0	1.5	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-0.51 (0.203)	-0.76 (0.144)	-0.18 (0.532)	-2.25 (0.703)	
95% CI [2]	-0.91, -0.11	-1.04, -0.47	-1.32, 0.96	-3.76, -0.74	
Difference (95% CI) in CFB [2]		-0.25 (-0.68, 0.19)		-2.07 (-3.21, -0.93)	
Hedges'G (95% CI) in CFB		-0.16 (-0.50, 0.17)		-1.08 (-2.33, -0.15)	
p-value [3]		0.266		0.002	
					0.005

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	2.4 (1.33)	2.4 (1.11)	2.1 (1.58)	2.9 (0.78)	
Median	3.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	2, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	2.1 (1.19)	1.8 (1.21)	1.8 (1.17)	1.8 (1.39)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	-0.16 (0.167)	-0.45 (0.120)	-0.61 (0.754)	-1.54 (0.957)	
95% CI [2]	-0.49, 0.17	-0.69, -0.21	-2.21, 0.99	-3.57, 0.48	
Difference (95% CI) in CFB [2]		-0.29 (-0.65, 0.07)		-0.93 (-2.43, 0.56)	
p-value [3]		0.113		0.203	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	118	10	9	
Mean (StdDev)	1.9 (1.38)	1.7 (1.14)	2.0 (1.33)	1.2 (0.97)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-0.41 (0.158)	-0.52 (0.113)	0.04 (0.699)	-1.54 (0.880)	
95% CI [2]	-0.72, -0.10	-0.75, -0.30	-1.45, 1.53	-3.42, 0.33	
Difference (95% CI) in CFB [2]		-0.11 (-0.46, 0.23)		-1.58 (-2.98, -0.19)	
p-value [3]		0.513		0.029	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	2.1 (1.36)	1.7 (1.23)	1.9 (1.35)	1.2 (0.97)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-0.32 (0.190)	-0.59 (0.135)	-0.56 (0.807)	-1.91 (1.076)	
95% CI [2]	-0.69, 0.06	-0.86, -0.33	-2.32, 1.20	-4.26, 0.43	
Difference (95% CI) in CFB [2]		-0.28 (-0.68, 0.13)		-1.35 (-3.32, 0.61)	
p-value [3]		0.177		0.159	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	54	117	9	8	
Mean (StdDev)	2.0 (1.36)	1.6 (1.25)	2.3 (1.12)	1.1 (0.99)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C5D1 CFB					
n	52	111	9	8	
LS Mean (StdErr) [2]	-0.27 (0.186)	-0.72 (0.135)	-0.20 (0.826)	-2.31 (1.071)	
95% CI [2]	-0.64, 0.10	-0.99, -0.45	-1.99, 1.58	-4.63, -0.00	
Difference (95% CI) in CFB [2]		-0.45 (-0.85, -0.05)		-2.11 (-3.91, -0.31)	
p-value [3]		0.029		0.025	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	2.1 (1.39)	1.6 (1.25)	2.4 (0.92)	0.9 (0.93)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-0.08 (0.189)	-0.70 (0.135)	-0.13 (0.747)	-2.71 (1.006)	
95% CI [2]	-0.45, 0.29	-0.96, -0.43	-1.74, 1.49	-4.88, -0.54	
Difference (95% CI) in CFB [2]		-0.62 (-1.03, -0.21)		-2.58 (-4.36, -0.80)	
p-value [3]		0.003		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	1.9 (1.35)	1.7 (1.30)	2.2 (1.32)	1.3 (0.89)	
Median	2.0	2.0	2.0	1.5	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-0.27 (0.193)	-0.62 (0.136)	-0.69 (0.766)	-2.67 (1.014)	
95% CI [2]	-0.65, 0.12	-0.89, -0.35	-2.33, 0.95	-4.84, -0.49	
Difference (95% CI) in CFB [2]		-0.35 (-0.77, 0.06)		-1.98 (-3.62, -0.33)	
Hedges'G (95% CI) in CFB		-0.25 (-0.59, 0.09)		-0.72 (-1.87, 0.22)	
p-value [3]		0.094		0.022	
					0.017

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	1.8 (1.54)	1.8 (1.48)	1.5 (1.63)	1.6 (1.59)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	1.8 (1.45)	1.6 (1.43)	1.4 (1.80)	1.0 (1.50)	
Median	2.0	1.0	0.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	0.02 (0.152)	-0.25 (0.109)	-0.26 (0.718)	-1.22 (0.910)	
95% CI [2]	-0.27, 0.32	-0.46, -0.03	-1.78, 1.27	-3.15, 0.71	
Difference (95% CI) in CFB [2]		-0.27 (-0.60, 0.06)		-0.96 (-2.38, 0.46)	
p-value [3]		0.105		0.171	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	118	10	9	
Mean (StdDev)	1.6 (1.53)	1.4 (1.40)	1.1 (1.66)	0.9 (1.17)	
Median	1.0	1.0	0.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-0.17 (0.156)	-0.33 (0.112)	-0.28 (0.752)	-1.28 (0.947)	
95% CI [2]	-0.48, 0.14	-0.55, -0.11	-1.88, 1.32	-3.30, 0.74	
Difference (95% CI) in CFB [2]		-0.16 (-0.51, 0.18)		-1.00 (-2.50, 0.50)	
p-value [3]		0.341		0.176	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	1.6 (1.32)	1.4 (1.39)	1.3 (1.60)	0.9 (1.36)	
Median	1.0	1.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-0.17 (0.204)	-0.40 (0.145)	-0.26 (0.573)	-0.52 (0.764)	
95% CI [2]	-0.58, 0.23	-0.68, -0.11	-1.51, 0.98	-2.19, 1.15	
Difference (95% CI) in CFB [2]		-0.22 (-0.66, 0.21)		-0.25 (-1.65, 1.14)	
p-value [3]		0.314		0.697	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	54	116	9	8	
Mean (StdDev)	1.4 (1.37)	1.3 (1.32)	1.2 (1.64)	0.9 (1.36)	
Median	1.0	1.0	0.0	0.5	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	52	110	9	8	
LS Mean (StdErr) [2]	-0.23 (0.194)	-0.48 (0.141)	-0.14 (0.997)	-0.98 (1.292)	
95% CI [2]	-0.61, 0.15	-0.76, -0.20	-2.29, 2.02	-3.78, 1.81	
Difference (95% CI) in CFB [2]		-0.25 (-0.67, 0.17)		-0.85 (-3.02, 1.33)	
p-value [3]		0.247		0.415	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	1.5 (1.40)	1.3 (1.43)	0.8 (1.16)	0.9 (1.36)	
Median	1.0	1.0	0.0	0.0	
Min, Max	0, 4	0, 4	0, 3	0, 3	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-0.23 (0.217)	-0.48 (0.155)	-0.45 (0.641)	-0.42 (0.863)	
95% CI [2]	-0.66, 0.20	-0.79, -0.18	-1.84, 0.94	-2.28, 1.45	
Difference (95% CI) in CFB [2]		-0.25 (-0.73, 0.22)		0.03 (-1.50, 1.56)	
p-value [3]		0.288		0.963	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	1.5 (1.45)	1.3 (1.42)	1.1 (1.20)	1.3 (1.39)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-0.10 (0.212)	-0.36 (0.150)	-0.07 (0.620)	-0.50 (0.821)	
95% CI [2]	-0.52, 0.32	-0.66, -0.07	-1.40, 1.26	-2.26, 1.26	
Difference (95% CI) in CFB [2]		-0.26 (-0.72, 0.19)		-0.43 (-1.76, 0.90)	
Hedges'G (95% CI) in CFB		-0.17 (-0.51, 0.17)		-0.19 (-1.23, 0.79)	
p-value [3]		0.253		0.501	
					0.870

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	2.2 (1.30)	2.4 (1.18)	2.1 (1.30)	1.8 (1.09)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	1.9 (1.19)	1.8 (1.19)	1.3 (1.27)	1.3 (1.12)	
Median	2.0	2.0	1.0	2.0	
Min, Max	0, 4	0, 4	0, 3	0, 3	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	-0.26 (0.136)	-0.49 (0.098)	-0.87 (0.365)	-0.43 (0.463)	
95% CI [2]	-0.53, 0.01	-0.68, -0.29	-1.64, -0.09	-1.41, 0.56	
Difference (95% CI) in CFB [2]		-0.23 (-0.52, 0.07)		0.44 (-0.28, 1.16)	
p-value [3]		0.130		0.216	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	118	10	9	
Mean (StdDev)	1.9 (1.29)	1.6 (1.27)	1.5 (1.27)	0.7 (0.71)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-0.25 (0.155)	-0.70 (0.111)	-0.61 (0.445)	-1.28 (0.561)	
95% CI [2]	-0.56, 0.05	-0.92, -0.48	-1.56, 0.34	-2.47, -0.08	
Difference (95% CI) in CFB [2]		-0.45 (-0.78, -0.11)		-0.67 (-1.56, 0.22)	
p-value [3]		0.010		0.131	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	1.9 (1.11)	1.6 (1.19)	1.4 (1.62)	0.9 (0.93)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-0.27 (0.156)	-0.73 (0.110)	-0.66 (0.500)	-1.15 (0.666)	
95% CI [2]	-0.58, 0.04	-0.95, -0.51	-1.75, 0.43	-2.60, 0.30	
Difference (95% CI) in CFB [2]		-0.46 (-0.79, -0.13)		-0.50 (-1.71, 0.72)	
p-value [3]		0.007		0.390	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	54	117	9	8	
Mean (StdDev)	1.8 (1.21)	1.5 (1.23)	1.7 (1.32)	0.6 (0.74)	
Median	2.0	1.0	1.0	0.5	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C5D1 CFB					
n	52	111	9	8	
LS Mean (StdErr) [2]	-0.48 (0.162)	-0.93 (0.118)	-0.48 (0.702)	-1.25 (0.910)	
95% CI [2]	-0.80, -0.16	-1.16, -0.70	-2.00, 1.03	-3.21, 0.72	
Difference (95% CI) in CFB [2]		-0.45 (-0.80, -0.10)		-0.76 (-2.30, 0.77)	
p-value [3]		0.012		0.301	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	2.1 (1.23)	1.5 (1.33)	1.9 (1.13)	0.7 (0.87)	
Median	2.0	1.0	2.0	0.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-0.16 (0.172)	-0.81 (0.123)	0.06 (0.536)	-0.62 (0.721)	
95% CI [2]	-0.50, 0.18	-1.05, -0.57	-1.10, 1.22	-2.18, 0.93	
Difference (95% CI) in CFB [2]		-0.65 (-1.02, -0.28)		-0.68 (-1.96, 0.59)	
p-value [3]		<0.001		0.269	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	1.9 (1.38)	1.5 (1.33)	1.6 (1.26)	1.0 (0.76)	
Median	2.0	1.0	1.5	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-0.21 (0.170)	-0.77 (0.120)	-0.56 (0.536)	-1.08 (0.710)	
95% CI [2]	-0.55, 0.12	-1.01, -0.53	-1.71, 0.59	-2.61, 0.44	
Difference (95% CI) in CFB [2]		-0.56 (-0.92, -0.19)		-0.52 (-1.67, 0.63)	
Hedges'G (95% CI) in CFB		-0.44 (-0.79, -0.11)		-0.27 (-1.32, 0.70)	
p-value [3]		0.003		0.345	
					>0.999

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	2.0 (1.38)	2.1 (1.29)	1.5 (1.51)	1.7 (1.32)	
Median	2.0	2.0	1.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	1.5 (1.20)	1.6 (1.27)	1.2 (1.17)	1.2 (1.09)	
Median	1.5	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 3	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	-0.37 (0.152)	-0.43 (0.110)	-0.67 (0.463)	-0.87 (0.588)	
95% CI [2]	-0.67, -0.07	-0.65, -0.22	-1.65, 0.31	-2.11, 0.38	
Difference (95% CI) in CFB [2]		-0.06 (-0.39, 0.27)		-0.20 (-1.11, 0.72)	
p-value [3]		0.724		0.658	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	118	10	9	
Mean (StdDev)	1.7 (1.30)	1.5 (1.29)	1.2 (1.14)	0.8 (0.97)	
Median	1.0	1.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-0.33 (0.154)	-0.58 (0.111)	-0.43 (0.481)	-1.18 (0.606)	
95% CI [2]	-0.64, -0.03	-0.80, -0.37	-1.46, 0.59	-2.47, 0.11	
Difference (95% CI) in CFB [2]		-0.25 (-0.59, 0.08)		-0.75 (-1.71, 0.21)	
p-value [3]		0.142		0.117	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	1.6 (1.15)	1.4 (1.25)	1.4 (1.27)	0.6 (0.73)	
Median	2.0	1.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-0.42 (0.157)	-0.70 (0.111)	-0.52 (0.628)	-1.08 (0.837)	
95% CI [2]	-0.73, -0.11	-0.92, -0.48	-1.89, 0.85	-2.90, 0.74	
Difference (95% CI) in CFB [2]		-0.28 (-0.61, 0.05)		-0.56 (-2.09, 0.96)	
p-value [3]		0.100		0.438	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	54	117	9	8	
Mean (StdDev)	1.5 (1.28)	1.3 (1.22)	1.7 (1.50)	0.6 (0.92)	
Median	1.0	1.0	2.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C5D1 CFB					
n	52	111	9	8	
LS Mean (StdErr) [2]	-0.44 (0.168)	-0.82 (0.122)	-0.19 (0.653)	-1.06 (0.846)	
95% CI [2]	-0.77, -0.10	-1.06, -0.58	-1.60, 1.22	-2.89, 0.77	
Difference (95% CI) in CFB [2]		-0.38 (-0.75, -0.01)		-0.88 (-2.30, 0.55)	
p-value [3]		0.042		0.207	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	1.7 (1.29)	1.4 (1.32)	1.3 (1.04)	0.4 (0.88)	
Median	2.0	1.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-0.24 (0.166)	-0.77 (0.118)	-0.93 (0.714)	-1.67 (0.961)	
95% CI [2]	-0.57, 0.08	-1.00, -0.54	-2.48, 0.61	-3.74, 0.41	
Difference (95% CI) in CFB [2]		-0.53 (-0.89, -0.17)		-0.73 (-2.44, 0.97)	
p-value [3]		0.004		0.369	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	1.6 (1.36)	1.3 (1.34)	1.1 (1.10)	0.5 (0.76)	
Median	2.0	1.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-0.18 (0.170)	-0.65 (0.120)	-0.98 (0.630)	-2.17 (0.833)	
95% CI [2]	-0.52, 0.15	-0.89, -0.41	-2.33, 0.37	-3.95, -0.38	
Difference (95% CI) in CFB [2]		-0.47 (-0.83, -0.10)		-1.19 (-2.54, 0.16)	
Hedges'G (95% CI) in CFB		-0.37 (-0.71, -0.04)		-0.53 (-1.63, 0.42)	
p-value [3]		0.013		0.080	
					0.377

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	3.0 (0.97)	2.8 (1.06)	2.8 (0.75)	2.9 (0.60)	
Median	3.0	3.0	3.0	3.0	
Min, Max	0, 4	0, 4	2, 4	2, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	2.5 (1.10)	2.4 (1.01)	2.5 (0.93)	2.7 (1.22)	
Median	3.0	2.0	2.0	3.0	
Min, Max	0, 4	0, 4	1, 4	1, 4	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	-0.48 (0.136)	-0.42 (0.098)	-0.77 (0.441)	-0.98 (0.560)	
95% CI [2]	-0.75, -0.21	-0.62, -0.23	-1.70, 0.17	-2.17, 0.21	
Difference (95% CI) in CFB [2]		0.06 (-0.24, 0.35)		-0.21 (-1.08, 0.66)	
p-value [3]		0.695		0.614	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	118	10	9	
Mean (StdDev)	2.5 (1.12)	2.2 (1.16)	2.9 (0.74)	2.0 (1.12)	
Median	3.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	2, 4	0, 3	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-0.48 (0.145)	-0.55 (0.104)	0.06 (0.547)	-0.94 (0.689)	
95% CI [2]	-0.76, -0.19	-0.76, -0.35	-1.11, 1.22	-2.41, 0.52	
Difference (95% CI) in CFB [2]		-0.07 (-0.39, 0.24)		-1.00 (-2.09, 0.09)	
p-value [3]		0.642		0.070	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	2.3 (1.29)	2.3 (1.22)	2.9 (0.69)	1.4 (0.88)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	2, 4	0, 2	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-0.68 (0.164)	-0.42 (0.117)	0.01 (0.500)	-1.38 (0.666)	
95% CI [2]	-1.01, -0.36	-0.65, -0.19	-1.08, 1.10	-2.83, 0.08	
Difference (95% CI) in CFB [2]		0.26 (-0.09, 0.61)		-1.39 (-2.60, -0.17)	
p-value [3]		0.148		0.029	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	117	9	8	
Mean (StdDev)	2.4 (1.12)	2.1 (1.26)	2.8 (0.83)	1.3 (1.28)	
Median	2.0	2.0	3.0	1.0	
Min, Max	0, 4	0, 4	2, 4	0, 3	
C5D1 CFB					
n	53	111	9	8	
LS Mean (StdErr) [2]	-0.60 (0.176)	-0.79 (0.128)	-0.54 (0.655)	-2.29 (0.849)	
95% CI [2]	-0.95, -0.25	-1.04, -0.53	-1.96, 0.87	-4.13, -0.46	
Difference (95% CI) in CFB [2]		-0.18 (-0.57, 0.20)		-1.75 (-3.18, -0.32)	
p-value [3]		0.342		0.020	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	2.5 (1.25)	2.2 (1.25)	2.8 (0.89)	1.3 (0.71)	
Median	2.0	2.0	2.5	1.0	
Min, Max	0, 4	0, 4	2, 4	0, 2	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-0.39 (0.177)	-0.58 (0.126)	-0.41 (0.490)	-1.96 (0.659)	
95% CI [2]	-0.74, -0.04	-0.83, -0.34	-1.47, 0.65	-3.38, -0.53	
Difference (95% CI) in CFB [2]		-0.20 (-0.58, 0.19)		-1.55 (-2.72, -0.38)	
p-value [3]		0.312		0.013	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	2.4 (1.18)	2.2 (1.18)	2.7 (0.82)	1.6 (0.74)	
Median	3.0	2.0	2.5	1.5	
Min, Max	0, 4	0, 4	2, 4	1, 3	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-0.49 (0.175)	-0.60 (0.124)	-0.43 (0.551)	-1.50 (0.728)	
95% CI [2]	-0.84, -0.15	-0.85, -0.36	-1.61, 0.75	-3.06, 0.06	
Difference (95% CI) in CFB [2]		-0.11 (-0.48, 0.27)		-1.07 (-2.25, 0.11)	
Hedges'G (95% CI) in CFB		-0.08 (-0.42, 0.25)		-0.54 (-1.65, 0.41)	
p-value [3]		0.567		0.072	
					0.078

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	2.3 (1.49)	2.5 (1.20)	2.9 (1.38)	2.0 (1.22)	
Median	3.0	2.5	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	2.2 (1.25)	2.0 (1.35)	2.2 (1.40)	1.7 (0.87)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	-0.21 (0.153)	-0.52 (0.110)	-1.26 (0.496)	-0.88 (0.629)	
95% CI [2]	-0.51, 0.09	-0.74, -0.30	-2.31, -0.20	-2.22, 0.45	
Difference (95% CI) in CFB [2]		-0.31 (-0.64, 0.02)		0.37 (-0.61, 1.36)	
p-value [3]		0.070		0.431	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	118	10	9	
Mean (StdDev)	2.2 (1.27)	1.9 (1.26)	2.3 (1.25)	0.8 (0.83)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-0.17 (0.170)	-0.63 (0.122)	-1.18 (0.609)	-2.10 (0.767)	
95% CI [2]	-0.51, 0.16	-0.87, -0.39	-2.48, 0.12	-3.73, -0.46	
Difference (95% CI) in CFB [2]		-0.46 (-0.83, -0.09)		-0.92 (-2.13, 0.30)	
p-value [3]		0.016		0.129	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	2.0 (1.36)	1.9 (1.39)	2.1 (1.46)	1.2 (1.09)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-0.34 (0.168)	-0.61 (0.119)	-1.28 (0.401)	-1.77 (0.535)	
95% CI [2]	-0.67, -0.01	-0.84, -0.37	-2.16, -0.41	-2.93, -0.60	
Difference (95% CI) in CFB [2]		-0.26 (-0.62, 0.09)		-0.48 (-1.46, 0.49)	
p-value [3]		0.148		0.301	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	117	9	8	
Mean (StdDev)	1.9 (1.51)	1.8 (1.44)	2.4 (1.33)	0.9 (0.83)	
Median	2.0	2.0	3.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C5D1 CFB					
n	53	111	9	8	
LS Mean (StdErr) [2]	-0.46 (0.177)	-0.74 (0.129)	-1.06 (0.355)	-2.04 (0.461)	
95% CI [2]	-0.81, -0.11	-0.99, -0.48	-1.83, -0.29	-3.04, -1.05	
Difference (95% CI) in CFB [2]		-0.28 (-0.66, 0.11)		-0.99 (-1.76, -0.21)	
p-value [3]		0.155		0.017	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	2.1 (1.34)	1.7 (1.37)	2.9 (1.25)	1.0 (0.87)	
Median	2.0	2.0	3.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-0.24 (0.174)	-0.83 (0.124)	-0.35 (0.456)	-1.58 (0.614)	
95% CI [2]	-0.58, 0.10	-1.07, -0.58	-1.34, 0.64	-2.91, -0.26	
Difference (95% CI) in CFB [2]		-0.59 (-0.96, -0.21)		-1.23 (-2.32, -0.15)	
p-value [3]		0.002		0.029	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	1.9 (1.42)	1.5 (1.40)	2.5 (1.65)	0.9 (1.25)	
Median	2.0	1.0	3.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-0.37 (0.184)	-0.83 (0.130)	-1.55 (0.566)	-2.67 (0.749)	
95% CI [2]	-0.74, -0.01	-1.08, -0.57	-2.76, -0.33	-4.27, -1.06	
Difference (95% CI) in CFB [2]		-0.46 (-0.85, -0.06)		-1.12 (-2.33, 0.10)	
Hedges'G (95% CI) in CFB		-0.33 (-0.68, -0.00)		-0.55 (-1.66, 0.40)	
p-value [3]		0.024		0.068	
					0.652

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	2.9 (1.09)	3.0 (0.99)	2.5 (1.29)	2.3 (0.71)	
Median	3.0	3.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	1, 3	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	2.3 (1.10)	2.2 (1.23)	1.8 (1.17)	1.6 (1.01)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	-0.55 (0.148)	-0.70 (0.107)	-0.88 (0.363)	-1.02 (0.460)	
95% CI [2]	-0.84, -0.26	-0.91, -0.49	-1.65, -0.11	-2.00, -0.05	
Difference (95% CI) in CFB [2]		-0.15 (-0.47, 0.17)		-0.15 (-0.86, 0.57)	
p-value [3]		0.354		0.671	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	118	10	9	
Mean (StdDev)	2.5 (1.15)	2.0 (1.20)	1.8 (1.32)	1.6 (0.88)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-0.37 (0.161)	-0.88 (0.116)	-0.75 (0.545)	-0.92 (0.687)	
95% CI [2]	-0.69, -0.05	-1.11, -0.65	-1.91, 0.41	-2.38, 0.55	
Difference (95% CI) in CFB [2]		-0.51 (-0.87, -0.16)		-0.17 (-1.26, 0.92)	
p-value [3]		0.004		0.749	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	2.5 (1.17)	2.1 (1.19)	2.4 (1.13)	0.8 (1.09)	
Median	2.0	2.0	2.0	0.0	
Min, Max	0, 4	0, 4	1, 4	0, 3	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-0.47 (0.166)	-0.86 (0.117)	-0.45 (0.611)	-1.71 (0.815)	
95% CI [2]	-0.80, -0.14	-1.09, -0.63	-1.78, 0.88	-3.49, 0.06	
Difference (95% CI) in CFB [2]		-0.39 (-0.75, -0.04)		-1.26 (-2.75, 0.22)	
p-value [3]		0.029		0.089	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	116	9	8	
Mean (StdDev)	2.3 (1.19)	2.0 (1.17)	2.6 (1.13)	0.9 (0.99)	
Median	2.0	2.0	3.0	0.5	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C5D1 CFB					
n	53	110	9	8	
LS Mean (StdErr) [2]	-0.59 (0.157)	-0.97 (0.114)	-0.28 (0.681)	-1.29 (0.883)	
95% CI [2]	-0.90, -0.28	-1.20, -0.75	-1.75, 1.20	-3.20, 0.62	
Difference (95% CI) in CFB [2]		-0.38 (-0.72, -0.04)		-1.01 (-2.50, 0.47)	
p-value [3]		0.027		0.164	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	2.5 (1.19)	1.9 (1.31)	2.5 (0.93)	1.2 (0.97)	
Median	2.5	2.0	2.5	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 3	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-0.39 (0.176)	-1.07 (0.125)	-0.42 (0.508)	-1.58 (0.684)	
95% CI [2]	-0.74, -0.04	-1.31, -0.82	-1.51, 0.68	-3.06, -0.11	
Difference (95% CI) in CFB [2]		-0.68 (-1.06, -0.30)		-1.17 (-2.38, 0.04)	
p-value [3]		<0.001		0.058	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	2.3 (1.28)	1.9 (1.30)	2.0 (1.49)	1.3 (1.04)	
Median	2.5	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-0.46 (0.172)	-0.93 (0.122)	-0.42 (0.655)	-0.58 (0.866)	
95% CI [2]	-0.80, -0.12	-1.17, -0.69	-1.82, 0.99	-2.44, 1.27	
Difference (95% CI) in CFB [2]		-0.47 (-0.84, -0.10)		-0.17 (-1.57, 1.24)	
Hedges'G (95% CI) in CFB		-0.37 (-0.71, -0.03)		-0.07 (-1.09, 0.92)	
p-value [3]		0.013		0.803	
					0.786

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	3.1 (0.92)	3.1 (0.98)	3.0 (1.00)	3.1 (0.78)	
Median	3.0	3.0	3.0	3.0	
Min, Max	0, 4	0, 4	1, 4	2, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	2.6 (0.94)	2.3 (1.08)	2.7 (1.27)	2.0 (1.22)	
Median	3.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 3	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	-0.44 (0.141)	-0.68 (0.101)	-0.68 (0.402)	-1.80 (0.510)	
95% CI [2]	-0.72, -0.16	-0.88, -0.48	-1.54, 0.17	-2.88, -0.71	
Difference (95% CI) in CFB [2]		-0.24 (-0.54, 0.07)		-1.11 (-1.91, -0.32)	
p-value [3]		0.125		0.009	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	118	10	9	
Mean (StdDev)	2.5 (1.10)	2.1 (1.17)	2.6 (1.07)	1.2 (0.97)	
Median	3.0	2.0	3.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 3	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-0.56 (0.164)	-0.86 (0.117)	-0.61 (0.486)	-2.28 (0.612)	
95% CI [2]	-0.88, -0.24	-1.10, -0.63	-1.65, 0.42	-3.58, -0.97	
Difference (95% CI) in CFB [2]		-0.30 (-0.66, 0.06)		-1.67 (-2.64, -0.70)	
p-value [3]		0.097		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	2.4 (1.15)	2.1 (1.13)	2.9 (1.21)	1.2 (1.09)	
Median	2.0	2.0	3.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 3	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-0.71 (0.158)	-0.98 (0.112)	-0.45 (0.650)	-2.71 (0.867)	
95% CI [2]	-1.03, -0.40	-1.20, -0.75	-1.87, 0.97	-4.60, -0.82	
Difference (95% CI) in CFB [2]		-0.26 (-0.60, 0.08)		-2.26 (-3.84, -0.68)	
p-value [3]		0.128		0.009	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	117	9	8	
Mean (StdDev)	2.3 (1.31)	2.1 (1.20)	2.9 (1.05)	1.3 (0.89)	
Median	2.0	2.0	3.0	1.5	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C5D1 CFB					
n	53	111	9	8	
LS Mean (StdErr) [2]	-0.71 (0.170)	-0.95 (0.124)	-0.81 (0.631)	-2.62 (0.818)	
95% CI [2]	-1.05, -0.38	-1.20, -0.71	-2.17, 0.55	-4.38, -0.85	
Difference (95% CI) in CFB [2]		-0.24 (-0.61, 0.13)		-1.81 (-3.18, -0.43)	
p-value [3]		0.201		0.014	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	2.5 (1.14)	2.0 (1.26)	3.0 (1.07)	1.0 (0.87)	
Median	2.0	2.0	3.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-0.56 (0.174)	-1.02 (0.124)	-0.77 (0.524)	-3.17 (0.705)	
95% CI [2]	-0.90, -0.22	-1.27, -0.78	-1.90, 0.36	-4.69, -1.64	
Difference (95% CI) in CFB [2]		-0.46 (-0.84, -0.08)		-2.40 (-3.65, -1.15)	
p-value [3]		0.017		0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	2.3 (1.33)	2.0 (1.25)	2.6 (1.35)	1.1 (0.83)	
Median	2.5	2.0	3.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-0.65 (0.182)	-0.96 (0.129)	-0.98 (0.573)	-2.67 (0.758)	
95% CI [2]	-1.01, -0.29	-1.22, -0.71	-2.21, 0.25	-4.29, -1.04	
Difference (95% CI) in CFB [2]		-0.32 (-0.71, 0.07)		-1.69 (-2.92, -0.46)	
Hedges'G (95% CI) in CFB		-0.23 (-0.57, 0.10)		-0.82 (-1.99, 0.11)	
p-value [3]		0.110		0.011	
					0.029

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	2.1 (1.44)	1.8 (1.48)	2.6 (1.75)	2.0 (1.22)	
Median	2.0	2.0	4.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	1.8 (1.41)	1.5 (1.41)	2.5 (1.44)	1.0 (1.00)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	-0.02 (0.171)	-0.15 (0.123)	0.24 (0.530)	-0.72 (0.673)	
95% CI [2]	-0.36, 0.32	-0.39, 0.09	-0.88, 1.37	-2.14, 0.71	
Difference (95% CI) in CFB [2]		-0.13 (-0.50, 0.24)		-0.96 (-2.01, 0.09)	
p-value [3]		0.500		0.070	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	118	10	9	
Mean (StdDev)	1.9 (1.36)	1.4 (1.38)	2.2 (1.62)	0.3 (0.71)	
Median	2.0	1.0	1.5	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-0.04 (0.186)	-0.30 (0.133)	-0.25 (0.661)	-1.75 (0.832)	
95% CI [2]	-0.41, 0.32	-0.56, -0.04	-1.66, 1.16	-3.52, 0.02	
Difference (95% CI) in CFB [2]		-0.25 (-0.66, 0.15)		-1.50 (-2.82, -0.18)	
p-value [3]		0.217		0.029	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	1.8 (1.23)	1.5 (1.39)	2.0 (1.73)	0.7 (1.12)	
Median	2.0	1.0	2.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-0.16 (0.182)	-0.21 (0.129)	-0.71 (0.640)	-1.94 (0.853)	
95% CI [2]	-0.52, 0.20	-0.46, 0.05	-2.10, 0.69	-3.80, -0.08	
Difference (95% CI) in CFB [2]		-0.05 (-0.43, 0.34)		-1.24 (-2.79, 0.32)	
p-value [3]		0.818		0.109	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	117	9	8	
Mean (StdDev)	1.7 (1.37)	1.5 (1.37)	2.0 (1.32)	0.1 (0.35)	
Median	2.0	1.0	1.0	0.0	
Min, Max	0, 4	0, 4	1, 4	0, 1	
C5D1 CFB					
n	53	111	9	8	
LS Mean (StdErr) [2]	-0.18 (0.195)	-0.23 (0.142)	-0.24 (0.766)	-1.78 (0.993)	
95% CI [2]	-0.56, 0.21	-0.51, 0.05	-1.90, 1.41	-3.93, 0.36	
Difference (95% CI) in CFB [2]		-0.05 (-0.47, 0.37)		-1.54 (-3.21, 0.13)	
p-value [3]		0.812		0.068	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	1.8 (1.45)	1.4 (1.33)	2.4 (1.41)	0.6 (0.88)	
Median	2.0	1.0	2.5	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-0.21 (0.203)	-0.34 (0.144)	-0.59 (0.771)	-2.04 (1.037)	
95% CI [2]	-0.61, 0.19	-0.62, -0.05	-2.26, 1.07	-4.28, 0.20	
Difference (95% CI) in CFB [2]		-0.13 (-0.57, 0.31)		-1.45 (-3.29, 0.39)	
p-value [3]		0.550		0.112	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	1.8 (1.52)	1.3 (1.33)	2.4 (1.26)	0.6 (0.74)	
Median	1.5	1.0	2.5	0.5	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	0.03 (0.206)	-0.25 (0.146)	-0.15 (0.722)	-1.92 (0.955)	
95% CI [2]	-0.38, 0.44	-0.54, 0.03	-1.70, 1.39	-3.96, 0.13	
Difference (95% CI) in CFB [2]		-0.28 (-0.73, 0.16)		-1.76 (-3.31, -0.21)	
Hedges'G (95% CI) in CFB		-0.19 (-0.52, 0.15)		-0.68 (-1.82, 0.26)	
p-value [3]		0.206		0.029	
					0.121

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	1.7 (1.26)	1.7 (1.29)	1.5 (1.21)	1.4 (1.59)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	1.5 (1.08)	1.3 (1.24)	1.3 (1.27)	1.0 (1.12)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 3	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	-0.28 (0.129)	-0.44 (0.093)	-0.59 (0.348)	-1.02 (0.441)	
95% CI [2]	-0.54, -0.03	-0.62, -0.25	-1.32, 0.15	-1.95, -0.08	
Difference (95% CI) in CFB [2]		-0.15 (-0.43, 0.13)		-0.43 (-1.12, 0.26)	
p-value [3]		0.286		0.202	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	118	10	9	
Mean (StdDev)	1.5 (1.18)	1.1 (1.19)	1.3 (1.16)	0.4 (0.53)	
Median	1.0	1.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 1	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-0.30 (0.165)	-0.68 (0.118)	-0.93 (0.598)	-2.01 (0.753)	
95% CI [2]	-0.62, 0.03	-0.91, -0.45	-2.21, 0.34	-3.62, -0.41	
Difference (95% CI) in CFB [2]		-0.38 (-0.74, -0.02)		-1.08 (-2.28, 0.11)	
p-value [3]		0.036		0.072	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	1.5 (1.15)	1.1 (1.17)	2.1 (1.35)	0.6 (0.88)	
Median	1.0	1.0	2.0	0.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-0.35 (0.170)	-0.69 (0.121)	-0.45 (0.663)	-2.05 (0.883)	
95% CI [2]	-0.69, -0.02	-0.93, -0.46	-1.89, 0.99	-3.97, -0.12	
Difference (95% CI) in CFB [2]		-0.34 (-0.70, 0.02)		-1.59 (-3.21, 0.02)	
p-value [3]		0.065		0.052	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	117	9	8	
Mean (StdDev)	1.4 (1.15)	1.0 (1.19)	1.8 (1.20)	0.5 (0.76)	
Median	1.0	1.0	2.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C5D1 CFB					
n	53	111	9	8	
LS Mean (StdErr) [2]	-0.42 (0.158)	-0.78 (0.115)	-0.69 (0.697)	-1.88 (0.903)	
95% CI [2]	-0.73, -0.11	-1.01, -0.56	-2.20, 0.82	-3.84, 0.07	
Difference (95% CI) in CFB [2]		-0.36 (-0.71, -0.02)		-1.19 (-2.72, 0.33)	
p-value [3]		0.038		0.114	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	1.4 (1.16)	1.1 (1.20)	1.9 (1.25)	0.6 (0.73)	
Median	1.0	1.0	2.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-0.35 (0.161)	-0.68 (0.114)	-0.21 (0.641)	-1.62 (0.863)	
95% CI [2]	-0.67, -0.04	-0.90, -0.45	-1.59, 1.18	-3.49, 0.24	
Difference (95% CI) in CFB [2]		-0.33 (-0.67, 0.02)		-1.42 (-2.94, 0.11)	
p-value [3]		0.066		0.067	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	1.3 (1.13)	1.0 (1.15)	1.2 (1.14)	0.8 (0.71)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-0.41 (0.170)	-0.67 (0.120)	-0.58 (0.488)	-1.42 (0.645)	
95% CI [2]	-0.75, -0.08	-0.91, -0.43	-1.63, 0.46	-2.80, -0.03	
Difference (95% CI) in CFB [2]		-0.26 (-0.62, 0.11)		-0.83 (-1.88, 0.21)	
Hedges'G (95% CI) in CFB		-0.20 (-0.54, 0.13)		-0.47 (-1.57, 0.48)	
p-value [3]		0.164		0.110	
					0.475

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	1.3 (1.32)	1.4 (1.44)	0.9 (1.04)	1.1 (1.69)	
Median	1.0	1.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	1.2 (1.39)	1.2 (1.34)	0.8 (0.98)	1.4 (1.51)	
Median	1.0	1.0	0.0	1.0	
Min, Max	0, 4	0, 4	0, 2	0, 4	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	0.02 (0.152)	-0.20 (0.109)	0.09 (0.522)	0.85 (0.662)	
95% CI [2]	-0.28, 0.32	-0.41, 0.02	-1.02, 1.19	-0.55, 2.25	
Difference (95% CI) in CFB [2]		-0.22 (-0.54, 0.11)		0.76 (-0.27, 1.80)	
p-value [3]		0.199		0.136	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	118	10	9	
Mean (StdDev)	1.0 (1.14)	0.9 (1.20)	0.8 (1.48)	0.9 (1.17)	
Median	1.0	0.0	0.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-0.14 (0.170)	-0.40 (0.121)	0.50 (0.477)	0.50 (0.601)	
95% CI [2]	-0.47, 0.20	-0.64, -0.16	-0.52, 1.52	-0.78, 1.78	
Difference (95% CI) in CFB [2]		-0.26 (-0.63, 0.11)		0.00 (-0.95, 0.95)	
p-value [3]		0.160		>0.999	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	1.2 (1.25)	1.0 (1.22)	2.0 (1.29)	0.6 (0.73)	
Median	1.0	1.0	1.0	0.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-0.18 (0.172)	-0.52 (0.122)	1.02 (0.628)	-0.42 (0.837)	
95% CI [2]	-0.52, 0.16	-0.76, -0.28	-0.35, 2.39	-2.24, 1.40	
Difference (95% CI) in CFB [2]		-0.34 (-0.71, 0.03)		-1.44 (-2.96, 0.09)	
p-value [3]		0.070		0.062	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	117	9	8	
Mean (StdDev)	1.1 (1.30)	0.9 (1.21)	1.2 (0.97)	0.5 (0.76)	
Median	1.0	0.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C5D1 CFB					
n	53	111	9	8	
LS Mean (StdErr) [2]	-0.11 (0.161)	-0.53 (0.118)	0.18 (0.463)	-0.58 (0.600)	
95% CI [2]	-0.43, 0.21	-0.76, -0.30	-0.82, 1.18	-1.88, 0.72	
Difference (95% CI) in CFB [2]		-0.42 (-0.77, -0.07)		-0.76 (-1.77, 0.25)	
p-value [3]		0.019		0.126	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	1.1 (1.23)	0.9 (1.18)	1.3 (1.28)	0.4 (0.73)	
Median	1.0	0.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-0.12 (0.164)	-0.54 (0.117)	0.65 (0.620)	-0.25 (0.835)	
95% CI [2]	-0.45, 0.20	-0.77, -0.31	-0.69, 1.99	-2.05, 1.55	
Difference (95% CI) in CFB [2]		-0.42 (-0.77, -0.06)		-0.90 (-2.38, 0.58)	
p-value [3]		0.022		0.211	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	1.2 (1.18)	0.9 (1.23)	0.8 (1.23)	0.6 (0.92)	
Median	1.0	0.0	0.0	0.0	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-0.02 (0.169)	-0.40 (0.119)	0.44 (0.549)	-0.08 (0.726)	
95% CI [2]	-0.35, 0.32	-0.64, -0.17	-0.74, 1.62	-1.64, 1.47	
Difference (95% CI) in CFB [2]		-0.39 (-0.75, -0.02)		-0.52 (-1.70, 0.65)	
Hedges'G (95% CI) in CFB		-0.31 (-0.65, 0.03)		-0.27 (-1.32, 0.71)	
p-value [3]		0.037		0.356	
					0.813

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	1.9 (1.16)	1.9 (1.27)	2.3 (1.10)	1.2 (1.56)	
Median	2.0	2.0	2.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	1.4 (1.28)	1.4 (1.27)	1.8 (1.08)	1.1 (1.05)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	-0.49 (0.157)	-0.63 (0.113)	-0.73 (0.515)	-0.52 (0.653)	
95% CI [2]	-0.80, -0.18	-0.86, -0.41	-1.82, 0.36	-1.90, 0.86	
Difference (95% CI) in CFB [2]		-0.14 (-0.48, 0.20)		0.21 (-0.81, 1.23)	
p-value [3]		0.411		0.665	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	118	10	9	
Mean (StdDev)	1.5 (1.07)	1.3 (1.13)	1.7 (1.42)	0.4 (0.73)	
Median	2.0	1.0	1.5	0.0	
Min, Max	0, 3	0, 4	0, 4	0, 2	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-0.41 (0.150)	-0.62 (0.108)	-0.68 (0.543)	-0.93 (0.684)	
95% CI [2]	-0.70, -0.11	-0.83, -0.40	-1.84, 0.48	-2.39, 0.53	
Difference (95% CI) in CFB [2]		-0.21 (-0.54, 0.12)		-0.25 (-1.33, 0.83)	
p-value [3]		0.208		0.630	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	1.4 (1.18)	1.4 (1.21)	2.4 (1.40)	0.4 (0.73)	
Median	1.0	1.0	3.0	0.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-0.50 (0.177)	-0.67 (0.126)	-0.17 (0.631)	-0.94 (0.841)	
95% CI [2]	-0.85, -0.15	-0.92, -0.42	-1.54, 1.21	-2.78, 0.89	
Difference (95% CI) in CFB [2]		-0.17 (-0.55, 0.21)		-0.78 (-2.31, 0.75)	
p-value [3]		0.380		0.291	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	117	9	8	
Mean (StdDev)	1.4 (1.28)	1.2 (1.18)	1.7 (1.50)	0.1 (0.35)	
Median	1.0	1.0	2.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 1	
C5D1 CFB					
n	53	111	9	8	
LS Mean (StdErr) [2]	-0.36 (0.164)	-0.76 (0.119)	-1.13 (0.679)	-1.66 (0.880)	
95% CI [2]	-0.69, -0.04	-0.99, -0.52	-2.60, 0.33	-3.56, 0.24	
Difference (95% CI) in CFB [2]		-0.39 (-0.75, -0.04)		-0.53 (-2.01, 0.95)	
p-value [3]		0.030		0.456	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	1.5 (1.30)	1.0 (1.12)	1.6 (1.30)	0.2 (0.44)	
Median	1.5	1.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 1	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-0.29 (0.171)	-1.02 (0.122)	-0.70 (0.722)	-1.17 (0.972)	
95% CI [2]	-0.63, 0.05	-1.26, -0.78	-2.26, 0.86	-3.27, 0.93	
Difference (95% CI) in CFB [2]		-0.73 (-1.10, -0.36)		-0.47 (-2.19, 1.26)	
p-value [3]		<0.001		0.568	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	1.5 (1.36)	1.1 (1.23)	1.6 (1.43)	0.4 (0.52)	
Median	2.0	1.0	1.5	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 1	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-0.18 (0.195)	-0.73 (0.138)	-0.81 (0.701)	-1.33 (0.928)	
95% CI [2]	-0.57, 0.21	-1.00, -0.46	-2.31, 0.69	-3.32, 0.66	
Difference (95% CI) in CFB [2]		-0.55 (-0.97, -0.13)		-0.52 (-2.03, 0.98)	
Hedges'G (95% CI) in CFB		-0.38 (-0.72, -0.05)		-0.21 (-1.25, 0.77)	
p-value [3]		0.010		0.467	
					0.713

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	2.2 (1.05)	2.2 (1.26)	2.7 (0.79)	1.9 (1.36)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	1.7 (1.10)	1.6 (1.29)	1.9 (1.30)	1.2 (1.09)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	-0.40 (0.151)	-0.56 (0.109)	-0.99 (0.565)	-1.07 (0.716)	
95% CI [2]	-0.70, -0.11	-0.78, -0.35	-2.19, 0.21	-2.59, 0.45	
Difference (95% CI) in CFB [2]		-0.16 (-0.49, 0.17)		-0.08 (-1.20, 1.04)	
p-value [3]		0.335		0.879	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	118	10	9	
Mean (StdDev)	1.7 (1.15)	1.4 (1.14)	2.0 (1.05)	1.0 (0.87)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-0.43 (0.161)	-0.77 (0.115)	-0.72 (0.717)	-0.72 (0.903)	
95% CI [2]	-0.75, -0.11	-0.99, -0.54	-2.25, 0.81	-2.65, 1.20	
Difference (95% CI) in CFB [2]		-0.34 (-0.69, 0.01)		0.00 (-1.43, 1.43)	
p-value [3]		0.059		>0.999	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	119	7	9	
Mean (StdDev)	1.6 (1.15)	1.5 (1.27)	2.4 (0.98)	0.8 (0.97)	
Median	2.0	1.0	2.0	0.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C4D1 CFB					
n	50	115	7	9	
LS Mean (StdErr) [2]	-0.61 (0.173)	-0.87 (0.123)	-0.99 (0.715)	-2.04 (0.953)	
95% CI [2]	-0.95, -0.27	-1.11, -0.63	-2.55, 0.57	-4.12, 0.03	
Difference (95% CI) in CFB [2]		-0.26 (-0.63, 0.11)		-1.05 (-2.79, 0.69)	
p-value [3]		0.167		0.212	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	117	9	8	
Mean (StdDev)	1.5 (1.26)	1.4 (1.22)	2.3 (1.50)	0.5 (0.76)	
Median	1.0	1.0	3.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C5D1 CFB					
n	53	111	9	8	
LS Mean (StdErr) [2]	-0.73 (0.178)	-0.90 (0.130)	-0.58 (0.819)	-1.44 (1.062)	
95% CI [2]	-1.08, -0.38	-1.16, -0.64	-2.35, 1.19	-3.73, 0.85	
Difference (95% CI) in CFB [2]		-0.17 (-0.55, 0.22)		-0.86 (-2.65, 0.93)	
p-value [3]		0.388		0.317	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	1.6 (1.24)	1.3 (1.27)	2.0 (1.41)	0.4 (0.53)	
Median	1.5	1.0	2.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 1	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-0.55 (0.182)	-0.95 (0.129)	-1.59 (0.573)	-3.04 (0.771)	
95% CI [2]	-0.91, -0.19	-1.20, -0.69	-2.83, -0.35	-4.71, -1.38	
Difference (95% CI) in CFB [2]		-0.40 (-0.79, -0.01)		-1.45 (-2.82, -0.08)	
p-value [3]		0.047		0.039	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	1.3 (1.18)	1.3 (1.27)	2.4 (1.07)	0.9 (0.64)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-0.69 (0.191)	-0.77 (0.135)	-0.57 (0.551)	-1.50 (0.728)	
95% CI [2]	-1.07, -0.31	-1.04, -0.50	-1.75, 0.61	-3.06, 0.06	
Difference (95% CI) in CFB [2]		-0.08 (-0.49, 0.33)		-0.93 (-2.11, 0.25)	
Hedges'G (95% CI) in CFB		-0.05 (-0.39, 0.28)		-0.47 (-1.56, 0.48)	
p-value [3]		0.712		0.114	
					0.222

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	2.7 (1.10)	2.6 (1.12)	2.1 (1.14)	2.3 (1.22)	
Median	3.0	3.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	2.4 (1.14)	2.2 (1.18)	1.8 (0.87)	2.0 (1.00)	
Median	2.5	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 3	0, 3	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	-0.27 (0.138)	-0.47 (0.100)	-0.66 (0.512)	-0.93 (0.650)	
95% CI [2]	-0.55, -0.00	-0.67, -0.28	-1.74, 0.43	-2.31, 0.44	
Difference (95% CI) in CFB [2]		-0.20 (-0.50, 0.10)		-0.28 (-1.29, 0.74)	
p-value [3]		0.193		0.571	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	119	10	9	
Mean (StdDev)	2.3 (1.14)	2.1 (1.17)	1.8 (1.14)	1.6 (0.73)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C3D1 CFB					
n	54	116	10	9	
LS Mean (StdErr) [2]	-0.42 (0.150)	-0.52 (0.107)	-0.99 (0.425)	-1.74 (0.535)	
95% CI [2]	-0.72, -0.12	-0.74, -0.31	-1.89, -0.08	-2.88, -0.59	
Difference (95% CI) in CFB [2]		-0.10 (-0.43, 0.22)		-0.75 (-1.60, 0.10)	
p-value [3]		0.530		0.079	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	2.3 (1.16)	2.0 (1.17)	2.3 (0.95)	1.3 (1.00)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 3	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-0.37 (0.170)	-0.62 (0.120)	-0.65 (0.610)	-2.20 (0.813)	
95% CI [2]	-0.71, -0.04	-0.86, -0.38	-1.98, 0.68	-3.97, -0.42	
Difference (95% CI) in CFB [2]		-0.25 (-0.61, 0.11)		-1.55 (-3.03, -0.07)	
p-value [3]		0.175		0.042	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	117	9	8	
Mean (StdDev)	2.2 (1.13)	2.0 (1.15)	2.4 (1.01)	1.1 (0.83)	
Median	2.0	2.0	3.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C5D1 CFB					
n	53	111	9	8	
LS Mean (StdErr) [2]	-0.51 (0.174)	-0.66 (0.127)	-0.61 (0.473)	-2.27 (0.614)	
95% CI [2]	-0.86, -0.17	-0.91, -0.41	-1.64, 0.41	-3.59, -0.94	
Difference (95% CI) in CFB [2]		-0.15 (-0.52, 0.23)		-1.65 (-2.69, -0.62)	
p-value [3]		0.443		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	2.3 (1.23)	1.8 (1.16)	2.4 (1.19)	1.2 (0.83)	
Median	2.0	2.0	2.5	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-0.36 (0.180)	-0.77 (0.128)	-1.04 (0.499)	-2.79 (0.671)	
95% CI [2]	-0.72, -0.01	-1.02, -0.52	-2.12, 0.04	-4.24, -1.34	
Difference (95% CI) in CFB [2]		-0.41 (-0.80, -0.02)		-1.75 (-2.94, -0.56)	
p-value [3]		0.041		0.007	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	2.3 (1.25)	1.8 (1.17)	2.0 (1.15)	1.6 (0.52)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	1, 2	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-0.33 (0.179)	-0.74 (0.127)	-0.31 (0.608)	-0.83 (0.804)	
95% CI [2]	-0.68, 0.03	-0.99, -0.49	-1.61, 0.99	-2.56, 0.89	
Difference (95% CI) in CFB [2]		-0.42 (-0.80, -0.03)		-0.52 (-1.83, 0.78)	
Hedges'G (95% CI) in CFB		-0.31 (-0.66, 0.02)		-0.24 (-1.28, 0.73)	
p-value [3]		0.034		0.403	
					0.683

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	2.1 (1.39)	2.0 (1.33)	2.4 (1.29)	2.2 (0.97)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	1.8 (1.33)	1.6 (1.29)	2.2 (1.08)	1.9 (1.62)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	-0.23 (0.143)	-0.39 (0.103)	-0.52 (0.574)	-0.70 (0.728)	
95% CI [2]	-0.52, 0.05	-0.59, -0.19	-1.74, 0.69	-2.24, 0.85	
Difference (95% CI) in CFB [2]		-0.16 (-0.47, 0.15)		-0.17 (-1.31, 0.96)	
p-value [3]		0.317		0.754	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	56	119	10	9	
Mean (StdDev)	1.6 (1.27)	1.5 (1.25)	2.1 (1.20)	1.3 (1.12)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C3D1 CFB					
n	53	116	10	9	
LS Mean (StdErr) [2]	-0.47 (0.154)	-0.50 (0.110)	-1.04 (0.472)	-1.79 (0.595)	
95% CI [2]	-0.77, -0.17	-0.71, -0.28	-2.05, -0.04	-3.06, -0.52	
Difference (95% CI) in CFB [2]		-0.02 (-0.36, 0.31)		-0.75 (-1.69, 0.19)	
p-value [3]		0.886		0.111	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	1.7 (1.37)	1.5 (1.30)	2.1 (1.21)	1.4 (1.33)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 3	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-0.49 (0.178)	-0.59 (0.126)	-0.99 (0.576)	-1.71 (0.767)	
95% CI [2]	-0.84, -0.14	-0.84, -0.34	-2.24, 0.26	-3.38, -0.04	
Difference (95% CI) in CFB [2]		-0.10 (-0.48, 0.28)		-0.72 (-2.12, 0.68)	
p-value [3]		0.604		0.285	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	117	9	8	
Mean (StdDev)	1.6 (1.34)	1.3 (1.25)	2.1 (1.27)	1.0 (1.07)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C5D1 CFB					
n	53	111	9	8	
LS Mean (StdErr) [2]	-0.50 (0.184)	-0.75 (0.134)	-0.98 (0.522)	-1.75 (0.677)	
95% CI [2]	-0.86, -0.13	-1.02, -0.49	-2.11, 0.14	-3.21, -0.28	
Difference (95% CI) in CFB [2]		-0.26 (-0.65, 0.14)		-0.76 (-1.90, 0.38)	
p-value [3]		0.208		0.171	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	1.8 (1.42)	1.3 (1.23)	2.0 (1.31)	1.0 (1.00)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-0.24 (0.184)	-0.75 (0.131)	-0.93 (0.395)	-1.67 (0.532)	
95% CI [2]	-0.60, 0.13	-1.01, -0.49	-1.79, -0.08	-2.82, -0.52	
Difference (95% CI) in CFB [2]		-0.51 (-0.91, -0.11)		-0.73 (-1.68, 0.21)	
p-value [3]		0.012		0.117	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	1.7 (1.37)	1.2 (1.32)	2.1 (1.37)	1.4 (1.19)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-0.36 (0.177)	-0.71 (0.125)	-0.51 (0.478)	-0.92 (0.632)	
95% CI [2]	-0.71, -0.01	-0.95, -0.46	-1.54, 0.51	-2.27, 0.44	
Difference (95% CI) in CFB [2]		-0.35 (-0.73, 0.03)		-0.40 (-1.43, 0.62)	
Hedges'G (95% CI) in CFB		-0.27 (-0.61, 0.07)		-0.24 (-1.28, 0.74)	
p-value [3]		0.072		0.411	
					0.805

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	57	126	11	9	
Mean (StdDev)	2.4 (1.06)	2.4 (1.08)	2.5 (0.93)	2.0 (1.58)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	1.8 (1.11)	1.8 (1.15)	2.0 (1.00)	1.6 (1.13)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C2D1 CFB					
n	55	123	11	9	
LS Mean (StdErr) [2]	-0.44 (0.159)	-0.65 (0.114)	-0.70 (0.506)	-0.73 (0.642)	
95% CI [2]	-0.75, -0.13	-0.87, -0.42	-1.77, 0.38	-2.09, 0.63	
Difference (95% CI) in CFB [2]		-0.21 (-0.55, 0.14)		-0.03 (-1.03, 0.97)	
p-value [3]		0.234		0.946	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	118	10	9	
Mean (StdDev)	1.8 (1.08)	1.7 (1.06)	2.4 (1.26)	1.0 (0.87)	
Median	2.0	2.0	2.5	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C3D1 CFB					
n	54	115	10	9	
LS Mean (StdErr) [2]	-0.54 (0.165)	-0.75 (0.118)	-0.26 (0.588)	-1.01 (0.740)	
95% CI [2]	-0.87, -0.22	-0.98, -0.51	-1.52, 0.99	-2.59, 0.56	
Difference (95% CI) in CFB [2]		-0.21 (-0.57, 0.15)		-0.75 (-1.92, 0.42)	
p-value [3]		0.260		0.193	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	1.8 (1.10)	1.7 (1.14)	2.6 (1.13)	1.0 (1.12)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 3	
C4D1 CFB					
n	50	116	7	9	
LS Mean (StdErr) [2]	-0.59 (0.173)	-0.83 (0.122)	-0.32 (0.612)	-0.93 (0.816)	
95% CI [2]	-0.94, -0.25	-1.07, -0.59	-1.66, 1.01	-2.71, 0.85	
Difference (95% CI) in CFB [2]		-0.23 (-0.60, 0.13)		-0.61 (-2.10, 0.88)	
p-value [3]		0.211		0.391	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	117	9	8	
Mean (StdDev)	1.7 (1.17)	1.5 (1.16)	2.3 (1.12)	0.9 (0.99)	
Median	2.0	1.0	3.0	0.5	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C5D1 CFB					
n	53	111	9	8	
LS Mean (StdErr) [2]	-0.75 (0.181)	-1.00 (0.132)	-0.37 (0.646)	-0.84 (0.837)	
95% CI [2]	-1.11, -0.39	-1.26, -0.74	-1.76, 1.03	-2.65, 0.97	
Difference (95% CI) in CFB [2]		-0.25 (-0.65, 0.14)		-0.47 (-1.88, 0.94)	
p-value [3]		0.206		0.482	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	1.8 (1.19)	1.5 (1.16)	2.3 (1.04)	1.0 (0.87)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C6D1 CFB					
n	52	114	8	9	
LS Mean (StdErr) [2]	-0.55 (0.177)	-1.00 (0.126)	-0.83 (0.646)	-1.21 (0.869)	
95% CI [2]	-0.90, -0.21	-1.25, -0.75	-2.22, 0.57	-3.09, 0.67	
Difference (95% CI) in CFB [2]		-0.45 (-0.83, -0.06)		-0.38 (-1.92, 1.16)	
p-value [3]		0.023		0.600	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	1.7 (1.27)	1.5 (1.28)	2.3 (1.25)	1.3 (0.89)	
Median	2.0	2.0	2.0	1.5	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C7D1 CFB					
n	50	113	10	8	
LS Mean (StdErr) [2]	-0.53 (0.209)	-0.92 (0.148)	-0.36 (0.748)	-1.00 (0.990)	
95% CI [2]	-0.95, -0.12	-1.22, -0.63	-1.96, 1.25	-3.12, 1.12	
Difference (95% CI) in CFB [2]		-0.39 (-0.84, 0.06)		-0.64 (-2.25, 0.96)	
Hedges'G (95% CI) in CFB		-0.25 (-0.59, 0.08)		-0.24 (-1.28, 0.74)	
p-value [3]		0.087		0.405	
					0.491

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	56	126	11	9	
Mean (StdDev)	2.1 (1.31)	2.2 (1.20)	2.0 (1.00)	1.8 (0.83)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 3	0, 3	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	1.8 (1.25)	1.8 (1.20)	2.1 (1.04)	1.8 (1.20)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 3	
C2D1 CFB					
n	54	123	11	9	
LS Mean (StdErr) [2]	-0.14 (0.155)	-0.43 (0.111)	0.43 (0.478)	0.25 (0.606)	
95% CI [2]	-0.45, 0.17	-0.65, -0.21	-0.59, 1.44	-1.04, 1.53	
Difference (95% CI) in CFB [2]		-0.29 (-0.63, 0.04)		-0.18 (-1.12, 0.77)	
p-value [3]		0.089		0.693	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	119	10	9	
Mean (StdDev)	1.7 (1.21)	1.6 (1.12)	2.3 (0.95)	1.0 (1.00)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C3D1 CFB					
n	53	116	10	9	
LS Mean (StdErr) [2]	-0.28 (0.148)	-0.58 (0.106)	1.15 (0.531)	0.24 (0.669)	
95% CI [2]	-0.58, 0.01	-0.79, -0.37	0.02, 2.28	-1.19, 1.66	
Difference (95% CI) in CFB [2]		-0.30 (-0.62, 0.03)		-0.92 (-1.98, 0.14)	
p-value [3]		0.071		0.085	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	1.6 (1.24)	1.6 (1.24)	2.4 (0.98)	1.2 (1.30)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 3	
C4D1 CFB					
n	49	116	7	9	
LS Mean (StdErr) [2]	-0.36 (0.174)	-0.69 (0.123)	1.20 (0.649)	0.48 (0.866)	
95% CI [2]	-0.70, -0.02	-0.93, -0.44	-0.22, 2.61	-1.40, 2.37	
Difference (95% CI) in CFB [2]		-0.33 (-0.70, 0.05)		-0.71 (-2.29, 0.87)	
p-value [3]		0.085		0.345	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	117	9	8	
Mean (StdDev)	1.5 (1.10)	1.5 (1.13)	2.1 (1.05)	0.8 (0.89)	
Median	1.0	1.0	2.0	0.5	
Min, Max	0, 4	0, 4	0, 3	0, 2	
C5D1 CFB					
n	52	111	9	8	
LS Mean (StdErr) [2]	-0.38 (0.172)	-0.70 (0.125)	1.07 (0.531)	0.30 (0.688)	
95% CI [2]	-0.72, -0.04	-0.95, -0.45	-0.07, 2.22	-1.19, 1.78	
Difference (95% CI) in CFB [2]		-0.32 (-0.69, 0.06)		-0.78 (-1.94, 0.38)	
p-value [3]		0.097		0.171	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	1.6 (1.20)	1.4 (1.22)	2.4 (1.06)	1.0 (0.71)	
Median	1.5	1.0	2.5	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 2	
C6D1 CFB					
n	51	114	8	9	
LS Mean (StdErr) [2]	-0.36 (0.179)	-0.85 (0.127)	0.81 (0.393)	-0.38 (0.529)	
95% CI [2]	-0.71, -0.00	-1.10, -0.60	-0.04, 1.66	-1.52, 0.77	
Difference (95% CI) in CFB [2]		-0.49 (-0.88, -0.10)		-1.18 (-2.12, -0.25)	
p-value [3]		0.014		0.017	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.1a
Change from Baseline in MC-QoL Individual Item Scores by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	1.6 (1.14)	1.5 (1.27)	2.0 (1.33)	1.0 (0.93)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 2	
C7D1 CFB					
n	49	113	10	8	
LS Mean (StdErr) [2]	-0.20 (0.190)	-0.58 (0.134)	0.98 (0.619)	0.17 (0.819)	
95% CI [2]	-0.58, 0.17	-0.85, -0.32	-0.35, 2.30	-1.59, 1.92	
Difference (95% CI) in CFB [2]		-0.38 (-0.79, 0.03)		-0.81 (-2.14, 0.52)	
Hedges'G (95% CI) in CFB		-0.27 (-0.62, 0.06)		-0.36 (-1.43, 0.60)	
p-value [3]		0.066		0.212	
					0.319

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-age-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	2.9 (1.12)	2.2 (1.12)	2.6 (1.17)	2.3 (1.13)	
Median	3.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	2.4 (1.15)	1.7 (0.95)	2.2 (1.03)	1.6 (0.95)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	-0.47 (0.274)	-0.39 (0.185)	-0.34 (0.168)	-0.70 (0.136)	
95% CI [2]	-1.02, 0.08	-0.76, -0.02	-0.68, -0.01	-0.97, -0.43	
Difference (95% CI) in CFB [2]		0.08 (-0.54, 0.69)		-0.35 (-0.72, 0.01)	
p-value [3]		0.799		0.057	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	94	
Mean (StdDev)	2.2 (1.29)	1.3 (0.91)	2.0 (1.09)	1.6 (0.98)	
Median	3.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-0.52 (0.344)	-0.66 (0.247)	-0.59 (0.181)	-0.71 (0.141)	
95% CI [2]	-1.21, 0.18	-1.16, -0.17	-0.95, -0.23	-0.99, -0.43	
Difference (95% CI) in CFB [2]		-0.15 (-0.93, 0.63)		-0.12 (-0.51, 0.27)	
p-value [3]		0.707		0.540	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	2.3 (1.22)	1.4 (0.80)	2.1 (1.06)	1.4 (1.10)	
Median	3.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	-0.50 (0.329)	-0.71 (0.231)	-0.44 (0.208)	-0.94 (0.159)	
95% CI [2]	-1.16, 0.16	-1.18, -0.25	-0.85, -0.03	-1.26, -0.63	
Difference (95% CI) in CFB [2]		-0.21 (-0.95, 0.52)		-0.50 (-0.95, -0.06)	
p-value [3]		0.562		0.025	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	88	
Mean (StdDev)	2.2 (1.09)	1.3 (0.95)	2.2 (1.23)	1.3 (1.01)	
Median	2.0	1.0	2.0	1.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	16	32	46	86	
LS Mean (StdErr) [2]	-0.54 (0.341)	-0.62 (0.252)	-0.32 (0.201)	-0.97 (0.158)	
95% CI [2]	-1.22, 0.15	-1.12, -0.11	-0.71, 0.08	-1.28, -0.65	
Difference (95% CI) in CFB [2]		-0.08 (-0.84, 0.69)		-0.65 (-1.09, -0.21)	
p-value [3]		0.840		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	2.3 (1.18)	1.5 (0.98)	2.0 (1.23)	1.4 (1.09)	
Median	3.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	-0.34 (0.360)	-0.40 (0.245)	-0.59 (0.193)	-0.93 (0.150)	
95% CI [2]	-1.06, 0.38	-0.89, 0.09	-0.97, -0.21	-1.23, -0.64	
Difference (95% CI) in CFB [2]		-0.06 (-0.86, 0.75)		-0.35 (-0.76, 0.07)	
p-value [3]		0.885		0.105	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	2.6 (1.21)	1.4 (1.00)	2.1 (1.15)	1.3 (1.00)	
Median	3.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	-0.22 (0.340)	-0.53 (0.237)	-0.43 (0.183)	-0.95 (0.143)	
95% CI [2]	-0.90, 0.47	-1.01, -0.06	-0.79, -0.06	-1.24, -0.67	
Difference (95% CI) in CFB [2]		-0.32 (-1.08, 0.45)		-0.53 (-0.92, -0.14)	
Hedges'G (95% CI) in CFB		-0.23 (-0.86, 0.39)		-0.40 (-0.78, -0.04)	
p-value [3]		0.408		0.009	
					0.581

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	2.8 (0.93)	1.8 (1.22)	2.4 (1.22)	2.2 (1.11)	
Median	3.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	2.2 (1.33)	1.4 (0.99)	2.1 (1.12)	1.4 (0.97)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	-0.44 (0.248)	-0.34 (0.167)	-0.11 (0.188)	-0.61 (0.152)	
95% CI [2]	-0.94, 0.06	-0.68, -0.01	-0.48, 0.26	-0.91, -0.31	
Difference (95% CI) in CFB [2]		0.10 (-0.45, 0.66)		-0.50 (-0.90, -0.09)	
p-value [3]		0.715		0.017	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	94	
Mean (StdDev)	2.1 (1.39)	1.1 (1.08)	2.1 (1.19)	1.5 (0.96)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-0.68 (0.301)	-0.63 (0.216)	-0.20 (0.202)	-0.58 (0.157)	
95% CI [2]	-1.29, -0.08	-1.07, -0.20	-0.60, 0.19	-0.89, -0.26	
Difference (95% CI) in CFB [2]		0.05 (-0.63, 0.73)		-0.37 (-0.81, 0.06)	
p-value [3]		0.878		0.094	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	2.3 (1.18)	1.2 (0.97)	2.0 (1.10)	1.3 (1.03)	
Median	3.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	-0.27 (0.352)	-0.53 (0.247)	-0.14 (0.194)	-0.73 (0.148)	
95% CI [2]	-0.98, 0.44	-1.03, -0.03	-0.52, 0.25	-1.02, -0.44	
Difference (95% CI) in CFB [2]		-0.26 (-1.05, 0.53)		-0.59 (-1.00, -0.18)	
p-value [3]		0.513		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	88	
Mean (StdDev)	2.1 (1.20)	1.3 (0.91)	2.0 (1.34)	1.4 (1.03)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	16	32	46	86	
LS Mean (StdErr) [2]	-0.56 (0.324)	-0.42 (0.240)	-0.13 (0.203)	-0.66 (0.160)	
95% CI [2]	-1.21, 0.09	-0.90, 0.07	-0.53, 0.27	-0.98, -0.34	
Difference (95% CI) in CFB [2]		0.14 (-0.58, 0.87)		-0.53 (-0.97, -0.09)	
p-value [3]		0.691		0.019	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	2.3 (1.11)	1.2 (0.93)	2.0 (1.22)	1.5 (1.12)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	-0.24 (0.343)	-0.52 (0.233)	-0.13 (0.199)	-0.62 (0.156)	
95% CI [2]	-0.93, 0.45	-0.99, -0.05	-0.52, 0.27	-0.93, -0.31	
Difference (95% CI) in CFB [2]		-0.28 (-1.05, 0.49)		-0.49 (-0.93, -0.06)	
p-value [3]		0.469		0.026	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	2.6 (1.03)	1.3 (1.10)	1.9 (1.25)	1.4 (1.10)	
Median	2.5	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	0.02 (0.337)	-0.38 (0.235)	-0.20 (0.211)	-0.62 (0.165)	
95% CI [2]	-0.66, 0.70	-0.85, 0.10	-0.62, 0.22	-0.95, -0.29	
Difference (95% CI) in CFB [2]		-0.39 (-1.15, 0.36)		-0.42 (-0.87, 0.03)	
Hedges'G (95% CI) in CFB		-0.29 (-0.93, 0.32)		-0.28 (-0.65, 0.08)	
p-value [3]		0.297		0.066	
					0.953

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	2.1 (1.00)	2.0 (1.11)	2.3 (1.17)	2.4 (1.07)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	1.9 (1.09)	1.7 (1.07)	2.1 (1.08)	1.9 (1.06)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	-0.06 (0.215)	-0.05 (0.144)	-0.23 (0.167)	-0.52 (0.135)	
95% CI [2]	-0.49, 0.37	-0.34, 0.24	-0.56, 0.10	-0.78, -0.25	
Difference (95% CI) in CFB [2]		0.01 (-0.47, 0.49)		-0.29 (-0.65, 0.07)	
p-value [3]		0.968		0.118	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	94	
Mean (StdDev)	1.6 (0.86)	1.6 (1.21)	2.1 (1.03)	1.8 (1.06)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-0.36 (0.260)	-0.36 (0.186)	-0.09 (0.193)	-0.47 (0.151)	
95% CI [2]	-0.89, 0.16	-0.74, 0.01	-0.48, 0.29	-0.77, -0.17	
Difference (95% CI) in CFB [2]		-0.00 (-0.59, 0.59)		-0.38 (-0.80, 0.04)	
p-value [3]		0.999		0.075	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	1.9 (1.13)	1.4 (0.99)	2.1 (1.12)	1.8 (1.01)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	-0.29 (0.263)	-0.64 (0.184)	-0.12 (0.208)	-0.52 (0.159)	
95% CI [2]	-0.82, 0.24	-1.01, -0.27	-0.53, 0.29	-0.84, -0.21	
Difference (95% CI) in CFB [2]		-0.35 (-0.94, 0.24)		-0.40 (-0.84, 0.04)	
p-value [3]		0.237		0.072	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	88	
Mean (StdDev)	1.6 (1.00)	1.4 (0.97)	2.1 (1.30)	1.8 (1.06)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	16	32	46	86	
LS Mean (StdErr) [2]	-0.35 (0.284)	-0.32 (0.210)	-0.17 (0.207)	-0.56 (0.164)	
95% CI [2]	-0.92, 0.22	-0.74, 0.10	-0.58, 0.24	-0.88, -0.23	
Difference (95% CI) in CFB [2]		0.03 (-0.61, 0.66)		-0.38 (-0.83, 0.07)	
p-value [3]		0.933		0.097	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	1.8 (0.77)	1.3 (0.98)	1.9 (1.27)	1.8 (1.13)	
Median	2.0	1.0	2.0	2.0	
Min, Max	1, 3	0, 3	0, 4	0, 4	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	-0.30 (0.291)	-0.62 (0.198)	-0.22 (0.201)	-0.55 (0.157)	
95% CI [2]	-0.88, 0.29	-1.02, -0.22	-0.62, 0.18	-0.86, -0.23	
Difference (95% CI) in CFB [2]		-0.32 (-0.97, 0.33)		-0.33 (-0.76, 0.11)	
p-value [3]		0.328		0.143	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	1.8 (1.00)	1.5 (1.03)	1.9 (1.18)	1.7 (1.11)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	-0.20 (0.362)	-0.29 (0.252)	-0.32 (0.208)	-0.72 (0.163)	
95% CI [2]	-0.93, 0.53	-0.80, 0.22	-0.74, 0.09	-1.04, -0.40	
Difference (95% CI) in CFB [2]		-0.09 (-0.90, 0.72)		-0.39 (-0.84, 0.05)	
Hedges'G (95% CI) in CFB		-0.06 (-0.69, 0.56)		-0.27 (-0.63, 0.10)	
p-value [3]		0.831		0.082	
					0.445

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	2.3 (1.34)	2.4 (1.06)	2.0 (1.18)	2.0 (1.27)	
Median	2.0	3.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	97	
Mean (StdDev)	1.7 (1.30)	1.8 (1.01)	1.7 (1.16)	1.4 (1.12)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	15	36	51	95	
LS Mean (StdErr) [2]	-0.56 (0.297)	-0.47 (0.200)	-0.19 (0.184)	-0.60 (0.151)	
95% CI [2]	-1.16, 0.04	-0.87, -0.06	-0.56, 0.17	-0.90, -0.30	
Difference (95% CI) in CFB [2]		0.09 (-0.57, 0.76)		-0.40 (-0.80, -0.01)	
p-value [3]		0.779		0.046	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	94	
Mean (StdDev)	1.6 (1.32)	1.7 (1.24)	1.8 (1.30)	1.4 (1.08)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-0.35 (0.287)	-0.34 (0.206)	-0.17 (0.210)	-0.68 (0.164)	
95% CI [2]	-0.93, 0.23	-0.75, 0.08	-0.58, 0.25	-1.01, -0.36	
Difference (95% CI) in CFB [2]		0.01 (-0.64, 0.66)		-0.52 (-0.97, -0.06)	
p-value [3]		0.966		0.026	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	1.9 (1.36)	1.7 (1.12)	1.7 (1.18)	1.3 (1.19)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	-0.33 (0.270)	-0.49 (0.189)	-0.31 (0.212)	-0.64 (0.162)	
95% CI [2]	-0.87, 0.22	-0.87, -0.11	-0.73, 0.11	-0.96, -0.32	
Difference (95% CI) in CFB [2]		-0.16 (-0.77, 0.44)		-0.33 (-0.78, 0.12)	
p-value [3]		0.585		0.152	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	88	
Mean (StdDev)	1.9 (1.14)	1.4 (0.83)	1.7 (1.10)	1.4 (1.27)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	16	32	46	86	
LS Mean (StdErr) [2]	-0.12 (0.268)	-0.84 (0.198)	-0.18 (0.217)	-0.66 (0.171)	
95% CI [2]	-0.66, 0.42	-1.24, -0.44	-0.61, 0.25	-1.00, -0.32	
Difference (95% CI) in CFB [2]		-0.72 (-1.32, -0.11)		-0.48 (-0.96, -0.01)	
p-value [3]		0.021		0.045	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	1.9 (1.39)	1.5 (1.06)	1.7 (1.13)	1.2 (1.14)	
Median	2.0	1.5	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	-0.08 (0.318)	-0.46 (0.217)	-0.23 (0.205)	-0.74 (0.160)	
95% CI [2]	-0.72, 0.56	-0.90, -0.02	-0.64, 0.17	-1.05, -0.42	
Difference (95% CI) in CFB [2]		-0.38 (-1.09, 0.34)		-0.51 (-0.95, -0.06)	
p-value [3]		0.294		0.026	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	2.1 (1.15)	1.7 (1.15)	1.5 (1.05)	1.3 (1.23)	
Median	2.0	1.5	2.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	0.09 (0.297)	-0.46 (0.207)	-0.19 (0.215)	-0.57 (0.168)	
95% CI [2]	-0.51, 0.69	-0.88, -0.04	-0.61, 0.24	-0.90, -0.23	
Difference (95% CI) in CFB [2]		-0.55 (-1.21, 0.12)		-0.38 (-0.83, 0.08)	
Hedges'G (95% CI) in CFB		-0.45 (-1.11, 0.16)		-0.25 (-0.61, 0.11)	
p-value [3]		0.104		0.105	
					0.693

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	3.0 (0.89)	2.8 (1.02)	3.2 (0.91)	3.3 (0.86)	
Median	3.0	3.0	3.0	4.0	
Min, Max	1, 4	1, 4	1, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	2.7 (1.01)	2.4 (0.99)	2.8 (0.94)	2.7 (1.10)	
Median	3.0	2.0	3.0	3.0	
Min, Max	1, 4	0, 4	1, 4	0, 4	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	-0.29 (0.254)	-0.35 (0.171)	-0.37 (0.152)	-0.58 (0.123)	
95% CI [2]	-0.80, 0.22	-0.69, -0.01	-0.67, -0.07	-0.82, -0.33	
Difference (95% CI) in CFB [2]		-0.06 (-0.63, 0.50)		-0.21 (-0.54, 0.12)	
p-value [3]		0.823		0.216	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	94	
Mean (StdDev)	2.7 (1.10)	2.0 (1.03)	2.6 (1.08)	2.6 (1.08)	
Median	3.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-0.27 (0.272)	-0.64 (0.195)	-0.49 (0.180)	-0.69 (0.141)	
95% CI [2]	-0.82, 0.28	-1.03, -0.25	-0.85, -0.14	-0.97, -0.41	
Difference (95% CI) in CFB [2]		-0.37 (-0.98, 0.25)		-0.19 (-0.58, 0.20)	
p-value [3]		0.232		0.328	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	2.8 (1.26)	2.2 (1.05)	2.7 (1.07)	2.5 (1.15)	
Median	3.0	2.0	3.0	3.0	
Min, Max	1, 4	0, 4	1, 4	0, 4	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	-0.22 (0.314)	-0.47 (0.220)	-0.50 (0.195)	-0.73 (0.149)	
95% CI [2]	-0.86, 0.41	-0.91, -0.03	-0.89, -0.12	-1.03, -0.44	
Difference (95% CI) in CFB [2]		-0.25 (-0.95, 0.46)		-0.23 (-0.65, 0.18)	
p-value [3]		0.484		0.266	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	88	
Mean (StdDev)	2.6 (1.22)	2.0 (1.00)	2.7 (1.20)	2.5 (1.15)	
Median	3.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	16	32	46	86	
LS Mean (StdErr) [2]	-0.25 (0.289)	-0.73 (0.214)	-0.53 (0.197)	-0.78 (0.155)	
95% CI [2]	-0.83, 0.33	-1.17, -0.30	-0.92, -0.14	-1.08, -0.47	
Difference (95% CI) in CFB [2]		-0.48 (-1.13, 0.17)		-0.25 (-0.67, 0.18)	
p-value [3]		0.142		0.256	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	2.5 (1.06)	2.0 (0.94)	2.6 (1.11)	2.4 (1.22)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	-0.68 (0.293)	-0.82 (0.199)	-0.56 (0.198)	-0.82 (0.155)	
95% CI [2]	-1.27, -0.09	-1.22, -0.42	-0.96, -0.17	-1.12, -0.51	
Difference (95% CI) in CFB [2]		-0.14 (-0.80, 0.52)		-0.25 (-0.68, 0.18)	
p-value [3]		0.668		0.246	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	2.6 (1.09)	2.3 (0.88)	2.6 (1.09)	2.3 (1.15)	
Median	2.5	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	-0.47 (0.300)	-0.45 (0.209)	-0.61 (0.195)	-0.88 (0.153)	
95% CI [2]	-1.08, 0.13	-0.87, -0.03	-0.99, -0.22	-1.18, -0.57	
Difference (95% CI) in CFB [2]		0.02 (-0.65, 0.70)		-0.27 (-0.69, 0.15)	
Hedges'G (95% CI) in CFB		0.02 (-0.60, 0.64)		-0.19 (-0.56, 0.17)	
p-value [3]		0.942		0.204	
					0.467

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	1.8 (1.00)	1.8 (1.12)	2.2 (1.13)	2.2 (1.11)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	1.6 (1.15)	1.7 (0.98)	2.0 (1.04)	1.8 (1.05)	
Median	1.5	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	-0.12 (0.173)	-0.02 (0.116)	-0.19 (0.162)	-0.43 (0.131)	
95% CI [2]	-0.47, 0.23	-0.25, 0.22	-0.51, 0.13	-0.69, -0.17	
Difference (95% CI) in CFB [2]		0.10 (-0.28, 0.49)		-0.24 (-0.59, 0.12)	
p-value [3]		0.593		0.187	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	94	
Mean (StdDev)	1.5 (1.01)	1.4 (1.08)	2.0 (1.10)	1.6 (0.97)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-0.37 (0.244)	-0.35 (0.175)	-0.22 (0.186)	-0.56 (0.145)	
95% CI [2]	-0.87, 0.12	-0.70, 0.00	-0.59, 0.15	-0.85, -0.27	
Difference (95% CI) in CFB [2]		0.02 (-0.53, 0.58)		-0.34 (-0.74, 0.07)	
p-value [3]		0.932		0.102	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	1.6 (1.18)	1.4 (1.08)	2.0 (1.20)	1.8 (1.16)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	-0.17 (0.280)	-0.19 (0.197)	-0.27 (0.199)	-0.45 (0.153)	
95% CI [2]	-0.74, 0.39	-0.58, 0.21	-0.66, 0.13	-0.76, -0.15	
Difference (95% CI) in CFB [2]		-0.02 (-0.64, 0.61)		-0.19 (-0.61, 0.24)	
p-value [3]		0.959		0.385	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	88	
Mean (StdDev)	1.6 (1.23)	1.2 (0.96)	2.0 (1.24)	1.8 (1.17)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	16	32	46	86	
LS Mean (StdErr) [2]	-0.12 (0.265)	-0.28 (0.197)	-0.32 (0.183)	-0.40 (0.144)	
95% CI [2]	-0.65, 0.41	-0.68, 0.12	-0.68, 0.04	-0.69, -0.12	
Difference (95% CI) in CFB [2]		-0.16 (-0.76, 0.44)		-0.08 (-0.48, 0.32)	
p-value [3]		0.591		0.683	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	1.6 (1.12)	1.2 (0.89)	1.9 (1.08)	1.7 (1.18)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	-0.26 (0.243)	-0.61 (0.165)	-0.28 (0.183)	-0.38 (0.143)	
95% CI [2]	-0.75, 0.23	-0.95, -0.28	-0.64, 0.08	-0.66, -0.09	
Difference (95% CI) in CFB [2]		-0.35 (-0.89, 0.20)		-0.10 (-0.50, 0.30)	
p-value [3]		0.206		0.617	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	1.4 (1.03)	1.3 (1.02)	1.9 (1.11)	1.7 (1.14)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	-0.30 (0.235)	-0.27 (0.164)	-0.35 (0.201)	-0.47 (0.157)	
95% CI [2]	-0.78, 0.17	-0.60, 0.06	-0.75, 0.05	-0.78, -0.16	
Difference (95% CI) in CFB [2]		0.03 (-0.50, 0.56)		-0.12 (-0.55, 0.31)	
Hedges'G (95% CI) in CFB		0.03 (-0.59, 0.66)		-0.08 (-0.45, 0.28)	
p-value [3]		0.910		0.586	
					0.707

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	2.2 (1.17)	2.4 (1.24)	2.9 (1.10)	2.8 (1.20)	
Median	2.0	3.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	97	
Mean (StdDev)	2.2 (1.11)	2.0 (1.11)	2.3 (1.07)	2.2 (1.15)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	15	36	51	95	
LS Mean (StdErr) [2]	0.03 (0.207)	-0.33 (0.139)	-0.37 (0.157)	-0.44 (0.129)	
95% CI [2]	-0.38, 0.45	-0.61, -0.05	-0.68, -0.06	-0.70, -0.19	
Difference (95% CI) in CFB [2]		-0.37 (-0.83, 0.10)		-0.07 (-0.40, 0.27)	
p-value [3]		0.118		0.695	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	94	
Mean (StdDev)	1.6 (1.06)	1.9 (1.16)	2.4 (1.09)	2.1 (1.25)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-0.55 (0.273)	-0.47 (0.196)	-0.43 (0.189)	-0.60 (0.147)	
95% CI [2]	-1.10, 0.00	-0.87, -0.08	-0.81, -0.06	-0.89, -0.31	
Difference (95% CI) in CFB [2]		0.07 (-0.54, 0.69)		-0.17 (-0.57, 0.24)	
p-value [3]		0.810		0.420	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	2.3 (0.96)	1.9 (1.09)	2.4 (1.18)	2.2 (1.26)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	0.01 (0.300)	-0.58 (0.210)	-0.35 (0.209)	-0.49 (0.160)	
95% CI [2]	-0.60, 0.61	-1.01, -0.16	-0.77, 0.06	-0.81, -0.17	
Difference (95% CI) in CFB [2]		-0.59 (-1.26, 0.08)		-0.14 (-0.58, 0.31)	
p-value [3]		0.083		0.538	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	88	
Mean (StdDev)	1.9 (1.09)	1.8 (1.06)	2.6 (1.07)	2.3 (1.27)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	16	32	46	86	
LS Mean (StdErr) [2]	-0.22 (0.274)	-0.57 (0.203)	-0.27 (0.189)	-0.51 (0.149)	
95% CI [2]	-0.77, 0.33	-0.98, -0.16	-0.64, 0.11	-0.80, -0.22	
Difference (95% CI) in CFB [2]		-0.35 (-0.97, 0.26)		-0.24 (-0.65, 0.17)	
p-value [3]		0.257		0.245	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	2.6 (1.06)	1.8 (1.09)	2.4 (1.23)	2.2 (1.24)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	0.38 (0.291)	-0.66 (0.198)	-0.43 (0.197)	-0.53 (0.154)	
95% CI [2]	-0.21, 0.96	-1.06, -0.26	-0.82, -0.04	-0.84, -0.23	
Difference (95% CI) in CFB [2]		-1.04 (-1.69, -0.39)		-0.11 (-0.53, 0.32)	
p-value [3]		0.002		0.627	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	1.9 (0.96)	2.0 (1.00)	2.3 (1.22)	2.1 (1.27)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	-0.20 (0.229)	-0.32 (0.160)	-0.44 (0.200)	-0.53 (0.156)	
95% CI [2]	-0.67, 0.26	-0.64, 0.00	-0.83, -0.04	-0.84, -0.22	
Difference (95% CI) in CFB [2]		-0.11 (-0.63, 0.40)		-0.09 (-0.52, 0.33)	
Hedges'G (95% CI) in CFB		-0.12 (-0.75, 0.50)		-0.06 (-0.43, 0.30)	
p-value [3]		0.655		0.671	
					0.995

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	2.0 (1.26)	2.5 (1.07)	2.3 (1.09)	2.6 (1.11)	
Median	2.0	3.0	2.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	52	98	
Mean (StdDev)	1.9 (1.24)	1.9 (0.90)	2.1 (1.18)	2.1 (1.21)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	15	36	50	96	
LS Mean (StdErr) [2]	0.08 (0.218)	-0.41 (0.147)	-0.18 (0.150)	-0.56 (0.121)	
95% CI [2]	-0.36, 0.52	-0.70, -0.11	-0.47, 0.12	-0.80, -0.32	
Difference (95% CI) in CFB [2]		-0.49 (-0.97, 0.00)		-0.38 (-0.71, -0.06)	
p-value [3]		0.051		0.022	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	94	
Mean (StdDev)	1.8 (1.30)	1.8 (0.90)	2.1 (1.18)	1.9 (1.21)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-0.15 (0.219)	-0.44 (0.157)	-0.13 (0.148)	-0.71 (0.116)	
95% CI [2]	-0.59, 0.29	-0.75, -0.12	-0.42, 0.16	-0.94, -0.48	
Difference (95% CI) in CFB [2]		-0.29 (-0.79, 0.20)		-0.58 (-0.90, -0.26)	
p-value [3]		0.243		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	1.7 (1.23)	1.8 (1.02)	2.1 (1.18)	2.0 (1.21)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	-0.17 (0.209)	-0.42 (0.147)	-0.19 (0.179)	-0.64 (0.137)	
95% CI [2]	-0.59, 0.25	-0.71, -0.12	-0.54, 0.17	-0.91, -0.37	
Difference (95% CI) in CFB [2]		-0.25 (-0.72, 0.22)		-0.46 (-0.84, -0.08)	
p-value [3]		0.286		0.019	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	88	
Mean (StdDev)	1.8 (1.20)	1.6 (0.80)	2.2 (1.24)	1.9 (1.24)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	16	32	46	86	
LS Mean (StdErr) [2]	-0.21 (0.257)	-0.67 (0.191)	-0.12 (0.177)	-0.62 (0.139)	
95% CI [2]	-0.73, 0.30	-1.05, -0.28	-0.47, 0.23	-0.90, -0.34	
Difference (95% CI) in CFB [2]		-0.45 (-1.03, 0.13)		-0.50 (-0.89, -0.12)	
p-value [3]		0.124		0.011	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	1.7 (1.35)	1.7 (0.93)	2.0 (1.19)	1.8 (1.31)	
Median	2.0	1.5	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	-0.23 (0.243)	-0.75 (0.165)	-0.29 (0.184)	-0.75 (0.144)	
95% CI [2]	-0.72, 0.26	-1.08, -0.42	-0.66, 0.07	-1.04, -0.47	
Difference (95% CI) in CFB [2]		-0.52 (-1.06, 0.02)		-0.46 (-0.86, -0.06)	
p-value [3]		0.061		0.025	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	1.8 (1.28)	1.8 (0.97)	2.0 (1.17)	1.7 (1.30)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	-0.06 (0.253)	-0.59 (0.177)	-0.19 (0.183)	-0.85 (0.143)	
95% CI [2]	-0.57, 0.45	-0.95, -0.23	-0.56, 0.17	-1.13, -0.57	
Difference (95% CI) in CFB [2]		-0.53 (-1.10, 0.04)		-0.66 (-1.04, -0.27)	
Hedges'G (95% CI) in CFB		-0.52 (-1.17, 0.09)		-0.50 (-0.88, -0.14)	
p-value [3]		0.066		0.001	
					0.705

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	1.6 (1.36)	1.8 (1.40)	2.1 (1.38)	2.2 (1.42)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	1.4 (1.21)	1.5 (1.25)	1.7 (1.43)	1.6 (1.39)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	-0.12 (0.357)	-0.13 (0.240)	-0.37 (0.221)	-0.60 (0.178)	
95% CI [2]	-0.84, 0.60	-0.61, 0.36	-0.81, 0.07	-0.95, -0.24	
Difference (95% CI) in CFB [2]		-0.01 (-0.81, 0.79)		-0.23 (-0.70, 0.25)	
p-value [3]		0.983		0.350	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	93	
Mean (StdDev)	1.6 (1.37)	1.6 (1.21)	1.8 (1.32)	1.5 (1.38)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-0.02 (0.419)	0.01 (0.301)	-0.28 (0.222)	-0.66 (0.173)	
95% CI [2]	-0.86, 0.82	-0.60, 0.62	-0.72, 0.16	-1.00, -0.32	
Difference (95% CI) in CFB [2]		0.03 (-0.92, 0.98)		-0.38 (-0.86, 0.10)	
p-value [3]		0.948		0.117	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	2.2 (0.94)	1.5 (1.11)	1.7 (1.31)	1.5 (1.36)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	0.36 (0.397)	-0.32 (0.279)	-0.30 (0.249)	-0.65 (0.191)	
95% CI [2]	-0.44, 1.16	-0.88, 0.25	-0.79, 0.20	-1.03, -0.27	
Difference (95% CI) in CFB [2]		-0.68 (-1.57, 0.21)		-0.35 (-0.88, 0.17)	
p-value [3]		0.130		0.188	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	46	89	
Mean (StdDev)	1.8 (1.24)	1.3 (1.20)	1.8 (1.23)	1.4 (1.31)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	16	32	45	87	
LS Mean (StdErr) [2]	0.03 (0.387)	-0.72 (0.287)	-0.22 (0.232)	-0.77 (0.181)	
95% CI [2]	-0.75, 0.81	-1.30, -0.14	-0.68, 0.24	-1.13, -0.42	
Difference (95% CI) in CFB [2]		-0.75 (-1.62, 0.12)		-0.55 (-1.06, -0.05)	
p-value [3]		0.090		0.033	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	1.8 (1.26)	1.3 (1.12)	1.9 (1.33)	1.4 (1.36)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	-0.13 (0.414)	-0.62 (0.282)	-0.16 (0.226)	-0.62 (0.177)	
95% CI [2]	-0.96, 0.71	-1.19, -0.05	-0.61, 0.29	-0.97, -0.27	
Difference (95% CI) in CFB [2]		-0.49 (-1.42, 0.44)		-0.46 (-0.96, 0.03)	
p-value [3]		0.290		0.064	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	1.9 (1.29)	1.4 (1.16)	1.5 (1.31)	1.3 (1.34)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	0.19 (0.387)	-0.40 (0.270)	-0.37 (0.227)	-0.71 (0.177)	
95% CI [2]	-0.59, 0.96	-0.94, 0.15	-0.82, 0.08	-1.06, -0.35	
Difference (95% CI) in CFB [2]		-0.58 (-1.45, 0.28)		-0.34 (-0.82, 0.15)	
Hedges'G (95% CI) in CFB		-0.37 (-1.02, 0.24)		-0.21 (-0.58, 0.15)	
p-value [3]		0.183		0.170	
					0.588

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	2.6 (1.09)	2.3 (1.29)	2.5 (1.31)	2.7 (1.27)	
Median	3.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	2.2 (1.11)	1.9 (1.20)	2.3 (1.27)	2.1 (1.36)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	-0.36 (0.331)	-0.33 (0.223)	-0.18 (0.178)	-0.62 (0.144)	
95% CI [2]	-1.03, 0.30	-0.78, 0.12	-0.54, 0.17	-0.90, -0.33	
Difference (95% CI) in CFB [2]		0.03 (-0.71, 0.77)		-0.43 (-0.82, -0.05)	
p-value [3]		0.930		0.028	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	93	
Mean (StdDev)	2.4 (1.27)	1.7 (1.27)	2.2 (1.20)	1.9 (1.32)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-0.13 (0.339)	-0.47 (0.243)	-0.27 (0.189)	-0.82 (0.148)	
95% CI [2]	-0.81, 0.55	-0.96, 0.02	-0.65, 0.10	-1.11, -0.52	
Difference (95% CI) in CFB [2]		-0.34 (-1.11, 0.42)		-0.54 (-0.95, -0.13)	
p-value [3]		0.372		0.010	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	2.3 (1.23)	1.9 (1.17)	2.0 (1.35)	2.0 (1.41)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	-0.13 (0.392)	-0.36 (0.275)	-0.42 (0.206)	-0.76 (0.158)	
95% CI [2]	-0.92, 0.66	-0.92, 0.19	-0.82, -0.01	-1.07, -0.45	
Difference (95% CI) in CFB [2]		-0.23 (-1.11, 0.64)		-0.34 (-0.78, 0.09)	
p-value [3]		0.597		0.121	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	46	89	
Mean (StdDev)	2.3 (1.21)	1.6 (1.00)	2.1 (1.23)	1.7 (1.33)	
Median	3.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	16	32	45	87	
LS Mean (StdErr) [2]	-0.14 (0.345)	-0.57 (0.256)	-0.36 (0.204)	-1.01 (0.159)	
95% CI [2]	-0.83, 0.56	-1.08, -0.05	-0.76, 0.05	-1.32, -0.69	
Difference (95% CI) in CFB [2]		-0.43 (-1.20, 0.35)		-0.65 (-1.10, -0.21)	
p-value [3]		0.272		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	2.7 (0.96)	1.7 (1.15)	2.2 (1.35)	1.7 (1.36)	
Median	3.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	0.10 (0.392)	-0.53 (0.267)	-0.19 (0.194)	-0.91 (0.151)	
95% CI [2]	-0.69, 0.89	-1.06, 0.01	-0.58, 0.19	-1.21, -0.61	
Difference (95% CI) in CFB [2]		-0.62 (-1.50, 0.26)		-0.72 (-1.14, -0.30)	
p-value [3]		0.160		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	2.6 (1.15)	1.8 (1.32)	2.0 (1.30)	1.7 (1.36)	
Median	3.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	0.05 (0.402)	-0.45 (0.280)	-0.47 (0.211)	-0.96 (0.164)	
95% CI [2]	-0.76, 0.86	-1.01, 0.12	-0.88, -0.05	-1.29, -0.64	
Difference (95% CI) in CFB [2]		-0.50 (-1.40, 0.40)		-0.49 (-0.94, -0.05)	
Hedges'G (95% CI) in CFB		-0.30 (-0.95, 0.31)		-0.33 (-0.70, 0.03)	
p-value [3]		0.270		0.031	
					0.991

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	2.2 (1.22)	2.3 (1.15)	2.4 (1.41)	2.4 (1.08)	
Median	2.5	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	2.0 (1.21)	1.7 (1.02)	2.1 (1.19)	1.9 (1.28)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	-0.23 (0.270)	-0.53 (0.182)	-0.14 (0.192)	-0.46 (0.156)	
95% CI [2]	-0.78, 0.31	-0.89, -0.16	-0.52, 0.25	-0.77, -0.16	
Difference (95% CI) in CFB [2]		-0.29 (-0.90, 0.31)		-0.33 (-0.75, 0.09)	
p-value [3]		0.333		0.120	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	93	
Mean (StdDev)	1.7 (1.36)	1.4 (1.08)	2.0 (1.38)	1.8 (1.14)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-0.34 (0.304)	-0.82 (0.218)	-0.28 (0.177)	-0.48 (0.138)	
95% CI [2]	-0.95, 0.27	-1.26, -0.38	-0.63, 0.07	-0.75, -0.21	
Difference (95% CI) in CFB [2]		-0.47 (-1.16, 0.21)		-0.20 (-0.59, 0.18)	
p-value [3]		0.172		0.297	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	2.1 (1.36)	1.4 (1.00)	2.0 (1.37)	1.8 (1.28)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	0.01 (0.343)	-0.79 (0.240)	-0.40 (0.217)	-0.61 (0.166)	
95% CI [2]	-0.68, 0.71	-1.27, -0.30	-0.83, 0.03	-0.94, -0.28	
Difference (95% CI) in CFB [2]		-0.80 (-1.57, -0.04)		-0.21 (-0.67, 0.25)	
p-value [3]		0.040		0.362	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	46	89	
Mean (StdDev)	1.9 (1.41)	1.3 (1.00)	2.1 (1.30)	1.7 (1.30)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	16	32	45	87	
LS Mean (StdErr) [2]	-0.30 (0.326)	-0.97 (0.241)	-0.10 (0.216)	-0.70 (0.169)	
95% CI [2]	-0.96, 0.35	-1.45, -0.48	-0.53, 0.32	-1.03, -0.36	
Difference (95% CI) in CFB [2]		-0.66 (-1.39, 0.07)		-0.59 (-1.06, -0.12)	
p-value [3]		0.075		0.014	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	2.3 (1.28)	1.2 (1.02)	2.1 (1.36)	1.7 (1.30)	
Median	3.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	0.13 (0.351)	-1.01 (0.239)	0.00 (0.214)	-0.67 (0.167)	
95% CI [2]	-0.58, 0.84	-1.49, -0.53	-0.42, 0.42	-1.00, -0.34	
Difference (95% CI) in CFB [2]		-1.14 (-1.93, -0.35)		-0.67 (-1.14, -0.21)	
p-value [3]		0.005		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	2.1 (1.26)	1.3 (1.05)	1.9 (1.37)	1.8 (1.35)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	0.05 (0.347)	-0.88 (0.242)	-0.23 (0.218)	-0.61 (0.171)	
95% CI [2]	-0.64, 0.75	-1.37, -0.39	-0.66, 0.21	-0.94, -0.27	
Difference (95% CI) in CFB [2]		-0.94 (-1.71, -0.16)		-0.38 (-0.84, 0.09)	
Hedges'G (95% CI) in CFB		-0.66 (-1.33, -0.05)		-0.24 (-0.61, 0.12)	
p-value [3]		0.019		0.109	
					0.241

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	1.4 (1.26)	1.7 (1.38)	1.8 (1.63)	1.9 (1.52)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	1.4 (1.20)	1.5 (1.23)	1.9 (1.58)	1.6 (1.51)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	0.03 (0.223)	-0.06 (0.150)	-0.04 (0.181)	-0.39 (0.146)	
95% CI [2]	-0.41, 0.48	-0.36, 0.25	-0.39, 0.32	-0.68, -0.10	
Difference (95% CI) in CFB [2]		-0.09 (-0.59, 0.41)		-0.35 (-0.74, 0.04)	
p-value [3]		0.721		0.075	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	93	
Mean (StdDev)	1.3 (1.36)	1.2 (1.33)	1.6 (1.62)	1.4 (1.41)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	0.08 (0.304)	-0.23 (0.218)	-0.27 (0.177)	-0.43 (0.138)	
95% CI [2]	-0.53, 0.69	-0.67, 0.21	-0.62, 0.08	-0.71, -0.16	
Difference (95% CI) in CFB [2]		-0.31 (-1.00, 0.37)		-0.16 (-0.55, 0.22)	
p-value [3]		0.365		0.397	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	1.5 (1.13)	1.3 (1.30)	1.6 (1.42)	1.3 (1.43)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	0.24 (0.329)	-0.21 (0.231)	-0.37 (0.227)	-0.51 (0.174)	
95% CI [2]	-0.42, 0.91	-0.68, 0.25	-0.82, 0.08	-0.86, -0.17	
Difference (95% CI) in CFB [2]		-0.46 (-1.19, 0.28)		-0.15 (-0.63, 0.33)	
p-value [3]		0.216		0.548	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	46	88	
Mean (StdDev)	1.2 (1.19)	1.1 (1.23)	1.5 (1.47)	1.4 (1.36)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	16	32	45	86	
LS Mean (StdErr) [2]	-0.06 (0.355)	-0.49 (0.263)	-0.25 (0.222)	-0.50 (0.174)	
95% CI [2]	-0.78, 0.65	-1.02, 0.04	-0.69, 0.19	-0.84, -0.16	
Difference (95% CI) in CFB [2]		-0.43 (-1.23, 0.37)		-0.25 (-0.73, 0.24)	
p-value [3]		0.285		0.316	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	1.3 (1.29)	0.9 (1.27)	1.4 (1.43)	1.5 (1.46)	
Median	2.0	0.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	0.08 (0.387)	-0.63 (0.263)	-0.40 (0.233)	-0.45 (0.182)	
95% CI [2]	-0.70, 0.86	-1.16, -0.10	-0.86, 0.06	-0.81, -0.09	
Difference (95% CI) in CFB [2]		-0.71 (-1.57, 0.16)		-0.05 (-0.56, 0.45)	
p-value [3]		0.108		0.839	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	1.4 (1.36)	1.4 (1.39)	1.5 (1.44)	1.3 (1.43)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	0.12 (0.309)	-0.17 (0.216)	-0.17 (0.238)	-0.47 (0.186)	
95% CI [2]	-0.51, 0.74	-0.60, 0.27	-0.64, 0.30	-0.84, -0.10	
Difference (95% CI) in CFB [2]		-0.28 (-0.98, 0.41)		-0.30 (-0.81, 0.21)	
Hedges'G (95% CI) in CFB		-0.23 (-0.86, 0.39)		-0.18 (-0.54, 0.19)	
p-value [3]		0.414		0.246	
					0.942

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	2.3 (1.30)	2.0 (1.09)	2.1 (1.30)	2.4 (1.19)	
Median	2.5	2.0	2.0	2.5	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	1.8 (1.17)	1.7 (1.01)	1.8 (1.25)	1.8 (1.25)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	-0.54 (0.206)	-0.37 (0.139)	-0.29 (0.151)	-0.51 (0.122)	
95% CI [2]	-0.95, -0.12	-0.64, -0.09	-0.59, 0.01	-0.76, -0.27	
Difference (95% CI) in CFB [2]		0.17 (-0.29, 0.63)		-0.23 (-0.55, 0.10)	
p-value [3]		0.454		0.171	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	93	
Mean (StdDev)	2.1 (1.48)	1.5 (1.19)	1.8 (1.22)	1.6 (1.29)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-0.08 (0.282)	-0.49 (0.203)	-0.29 (0.163)	-0.78 (0.128)	
95% CI [2]	-0.65, 0.49	-0.90, -0.08	-0.61, 0.04	-1.03, -0.52	
Difference (95% CI) in CFB [2]		-0.41 (-1.05, 0.23)		-0.49 (-0.84, -0.13)	
p-value [3]		0.207		0.007	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	2.1 (1.28)	1.3 (1.01)	1.8 (1.15)	1.6 (1.24)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	-0.17 (0.270)	-0.62 (0.189)	-0.35 (0.172)	-0.80 (0.132)	
95% CI [2]	-0.72, 0.37	-1.00, -0.24	-0.69, -0.01	-1.06, -0.54	
Difference (95% CI) in CFB [2]		-0.44 (-1.05, 0.16)		-0.45 (-0.81, -0.08)	
p-value [3]		0.144		0.016	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	46	89	
Mean (StdDev)	1.9 (1.30)	1.2 (0.89)	1.7 (1.19)	1.6 (1.32)	
Median	2.0	1.0	1.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	16	32	45	87	
LS Mean (StdErr) [2]	-0.31 (0.292)	-0.85 (0.216)	-0.47 (0.183)	-0.98 (0.143)	
95% CI [2]	-0.90, 0.28	-1.28, -0.41	-0.83, -0.11	-1.26, -0.70	
Difference (95% CI) in CFB [2]		-0.53 (-1.19, 0.12)		-0.51 (-0.91, -0.11)	
p-value [3]		0.109		0.012	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	2.3 (1.33)	1.2 (1.06)	2.0 (1.18)	1.6 (1.40)	
Median	3.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	-0.04 (0.314)	-0.82 (0.213)	-0.15 (0.187)	-0.83 (0.146)	
95% CI [2]	-0.67, 0.60	-1.25, -0.39	-0.52, 0.22	-1.12, -0.54	
Difference (95% CI) in CFB [2]		-0.78 (-1.49, -0.08)		-0.68 (-1.08, -0.27)	
p-value [3]		0.030		0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	2.2 (1.28)	1.5 (1.08)	1.8 (1.39)	1.4 (1.39)	
Median	3.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	-0.01 (0.273)	-0.46 (0.190)	-0.31 (0.186)	-0.93 (0.146)	
95% CI [2]	-0.57, 0.54	-0.85, -0.08	-0.67, 0.06	-1.22, -0.64	
Difference (95% CI) in CFB [2]		-0.45 (-1.06, 0.16)		-0.63 (-1.02, -0.23)	
Hedges'G (95% CI) in CFB		-0.40 (-1.05, 0.21)		-0.47 (-0.85, -0.11)	
p-value [3]		0.148		0.002	
					0.594

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	2.1 (1.34)	1.8 (1.12)	1.9 (1.42)	2.2 (1.35)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	1.4 (1.09)	1.4 (1.09)	1.5 (1.23)	1.7 (1.32)	
Median	1.5	1.0	1.0	1.5	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	-0.40 (0.236)	-0.34 (0.159)	-0.41 (0.168)	-0.51 (0.136)	
95% CI [2]	-0.88, 0.07	-0.66, -0.02	-0.74, -0.08	-0.78, -0.24	
Difference (95% CI) in CFB [2]		0.07 (-0.46, 0.60)		-0.10 (-0.46, 0.27)	
p-value [3]		0.798		0.598	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	93	
Mean (StdDev)	1.8 (1.52)	1.2 (1.17)	1.5 (1.20)	1.5 (1.31)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-0.14 (0.261)	-0.56 (0.187)	-0.35 (0.170)	-0.63 (0.133)	
95% CI [2]	-0.66, 0.39	-0.93, -0.18	-0.68, -0.01	-0.89, -0.37	
Difference (95% CI) in CFB [2]		-0.42 (-1.01, 0.17)		-0.28 (-0.65, 0.09)	
p-value [3]		0.159		0.131	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	1.6 (1.35)	1.1 (0.94)	1.6 (1.10)	1.4 (1.33)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	-0.38 (0.275)	-0.75 (0.193)	-0.42 (0.178)	-0.72 (0.136)	
95% CI [2]	-0.94, 0.17	-1.14, -0.37	-0.77, -0.07	-0.99, -0.45	
Difference (95% CI) in CFB [2]		-0.37 (-0.98, 0.24)		-0.30 (-0.68, 0.07)	
p-value [3]		0.231		0.114	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	46	89	
Mean (StdDev)	1.6 (1.23)	0.9 (0.89)	1.5 (1.35)	1.4 (1.30)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C5D1 CFB					
n	16	32	45	87	
LS Mean (StdErr) [2]	-0.30 (0.264)	-0.79 (0.195)	-0.34 (0.196)	-0.82 (0.153)	
95% CI [2]	-0.84, 0.23	-1.19, -0.40	-0.73, 0.05	-1.12, -0.52	
Difference (95% CI) in CFB [2]		-0.49 (-1.08, 0.10)		-0.48 (-0.91, -0.05)	
p-value [3]		0.103		0.027	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	1.8 (1.42)	1.0 (1.01)	1.6 (1.23)	1.5 (1.40)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	-0.16 (0.296)	-0.78 (0.202)	-0.28 (0.189)	-0.83 (0.147)	
95% CI [2]	-0.75, 0.44	-1.19, -0.37	-0.66, 0.09	-1.12, -0.54	
Difference (95% CI) in CFB [2]		-0.62 (-1.29, 0.04)		-0.54 (-0.95, -0.13)	
p-value [3]		0.066		0.010	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	1.7 (1.35)	1.2 (1.10)	1.5 (1.33)	1.3 (1.41)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	-0.23 (0.291)	-0.57 (0.203)	-0.17 (0.191)	-0.75 (0.150)	
95% CI [2]	-0.81, 0.36	-0.97, -0.16	-0.55, 0.20	-1.05, -0.45	
Difference (95% CI) in CFB [2]		-0.34 (-0.99, 0.31)		-0.58 (-0.98, -0.17)	
Hedges'G (95% CI) in CFB		-0.29 (-0.93, 0.33)		-0.42 (-0.80, -0.06)	
p-value [3]		0.302		0.006	
					0.519

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	3.0 (0.82)	2.7 (1.02)	3.0 (0.98)	2.9 (1.04)	
Median	3.0	3.0	3.0	3.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	2.6 (0.96)	2.5 (1.00)	2.5 (1.10)	2.4 (1.04)	
Median	2.5	3.0	3.0	2.0	
Min, Max	1, 4	1, 4	0, 4	0, 4	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	-0.48 (0.235)	-0.24 (0.158)	-0.50 (0.149)	-0.52 (0.120)	
95% CI [2]	-0.96, -0.01	-0.55, 0.08	-0.79, -0.21	-0.75, -0.28	
Difference (95% CI) in CFB [2]		0.25 (-0.28, 0.77)		-0.02 (-0.34, 0.31)	
p-value [3]		0.348		0.925	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	93	
Mean (StdDev)	2.4 (1.06)	2.1 (0.95)	2.6 (1.09)	2.2 (1.22)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-0.49 (0.222)	-0.49 (0.160)	-0.32 (0.168)	-0.59 (0.131)	
95% CI [2]	-0.93, -0.04	-0.82, -0.17	-0.65, 0.01	-0.85, -0.33	
Difference (95% CI) in CFB [2]		-0.01 (-0.51, 0.50)		-0.27 (-0.63, 0.09)	
p-value [3]		0.975		0.145	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	2.3 (1.23)	2.1 (1.20)	2.4 (1.27)	2.3 (1.23)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	-0.45 (0.312)	-0.32 (0.219)	-0.62 (0.181)	-0.53 (0.138)	
95% CI [2]	-1.08, 0.18	-0.76, 0.12	-0.97, -0.26	-0.80, -0.26	
Difference (95% CI) in CFB [2]		0.13 (-0.57, 0.83)		0.09 (-0.30, 0.47)	
p-value [3]		0.711		0.659	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	89	
Mean (StdDev)	2.3 (1.26)	1.9 (1.06)	2.5 (1.02)	2.1 (1.35)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C5D1 CFB					
n	16	32	46	87	
LS Mean (StdErr) [2]	-0.71 (0.309)	-0.84 (0.229)	-0.44 (0.198)	-0.82 (0.155)	
95% CI [2]	-1.34, -0.09	-1.30, -0.38	-0.83, -0.05	-1.13, -0.51	
Difference (95% CI) in CFB [2]		-0.12 (-0.82, 0.57)		-0.38 (-0.81, 0.05)	
p-value [3]		0.723		0.081	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	2.4 (1.18)	1.9 (1.07)	2.5 (1.23)	2.2 (1.30)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	-0.42 (0.279)	-0.78 (0.190)	-0.26 (0.200)	-0.57 (0.157)	
95% CI [2]	-0.99, 0.14	-1.16, -0.40	-0.65, 0.14	-0.88, -0.26	
Difference (95% CI) in CFB [2]		-0.36 (-0.98, 0.27)		-0.31 (-0.74, 0.13)	
p-value [3]		0.255		0.165	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	2.3 (1.20)	1.9 (0.87)	2.5 (1.11)	2.2 (1.27)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	-0.61 (0.300)	-0.78 (0.209)	-0.33 (0.192)	-0.57 (0.150)	
95% CI [2]	-1.21, -0.00	-1.20, -0.36	-0.71, 0.05	-0.87, -0.28	
Difference (95% CI) in CFB [2]		-0.18 (-0.85, 0.49)		-0.24 (-0.65, 0.17)	
Hedges'G (95% CI) in CFB		-0.15 (-0.78, 0.47)		-0.18 (-0.54, 0.18)	
p-value [3]		0.598		0.243	
					0.849

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	2.3 (1.54)	2.4 (1.01)	2.4 (1.47)	2.5 (1.28)	
Median	2.5	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	2.1 (1.39)	1.8 (1.24)	2.2 (1.24)	2.0 (1.35)	
Median	2.5	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	-0.17 (0.283)	-0.56 (0.190)	-0.34 (0.166)	-0.51 (0.134)	
95% CI [2]	-0.74, 0.40	-0.94, -0.18	-0.67, -0.02	-0.77, -0.24	
Difference (95% CI) in CFB [2]		-0.39 (-1.02, 0.24)		-0.16 (-0.52, 0.19)	
p-value [3]		0.223		0.365	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	93	
Mean (StdDev)	2.0 (1.50)	1.5 (1.11)	2.3 (1.17)	1.9 (1.31)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-0.38 (0.293)	-0.98 (0.210)	-0.11 (0.189)	-0.51 (0.147)	
95% CI [2]	-0.97, 0.21	-1.41, -0.56	-0.49, 0.26	-0.80, -0.22	
Difference (95% CI) in CFB [2]		-0.61 (-1.27, 0.06)		-0.40 (-0.81, 0.01)	
p-value [3]		0.072		0.055	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	1.9 (1.60)	1.6 (1.20)	2.1 (1.28)	1.9 (1.44)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	-0.43 (0.295)	-0.71 (0.207)	-0.32 (0.183)	-0.55 (0.140)	
95% CI [2]	-1.02, 0.16	-1.13, -0.30	-0.68, 0.05	-0.83, -0.28	
Difference (95% CI) in CFB [2]		-0.28 (-0.94, 0.38)		-0.24 (-0.63, 0.15)	
p-value [3]		0.390		0.230	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	89	
Mean (StdDev)	1.7 (1.69)	1.6 (1.27)	2.1 (1.42)	1.8 (1.48)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	16	32	46	87	
LS Mean (StdErr) [2]	-0.65 (0.292)	-0.88 (0.216)	-0.30 (0.188)	-0.66 (0.148)	
95% CI [2]	-1.24, -0.07	-1.32, -0.45	-0.68, 0.07	-0.96, -0.37	
Difference (95% CI) in CFB [2]		-0.23 (-0.88, 0.43)		-0.36 (-0.77, 0.05)	
p-value [3]		0.489		0.084	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	2.2 (1.57)	1.3 (1.15)	2.2 (1.28)	1.7 (1.42)	
Median	3.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	-0.10 (0.287)	-1.01 (0.195)	-0.16 (0.192)	-0.74 (0.150)	
95% CI [2]	-0.68, 0.48	-1.40, -0.61	-0.54, 0.22	-1.04, -0.45	
Difference (95% CI) in CFB [2]		-0.91 (-1.55, -0.27)		-0.58 (-1.00, -0.16)	
p-value [3]		0.007		0.007	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	1.8 (1.56)	1.2 (1.28)	2.1 (1.43)	1.6 (1.43)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	-0.55 (0.325)	-1.12 (0.227)	-0.25 (0.202)	-0.72 (0.158)	
95% CI [2]	-1.21, 0.10	-1.58, -0.67	-0.65, 0.15	-1.03, -0.40	
Difference (95% CI) in CFB [2]		-0.57 (-1.30, 0.16)		-0.46 (-0.89, -0.03)	
Hedges'G (95% CI) in CFB		-0.43 (-1.08, 0.18)		-0.32 (-0.69, 0.04)	
p-value [3]		0.122		0.035	
					0.756

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	2.8 (0.93)	2.8 (0.91)	2.8 (1.18)	2.9 (1.02)	
Median	3.0	3.0	3.0	3.0	
Min, Max	1, 4	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	2.3 (1.18)	2.0 (1.22)	2.3 (1.11)	2.3 (1.22)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	-0.50 (0.258)	-0.69 (0.173)	-0.61 (0.158)	-0.71 (0.128)	
95% CI [2]	-1.02, 0.02	-1.04, -0.35	-0.92, -0.30	-0.97, -0.46	
Difference (95% CI) in CFB [2]		-0.19 (-0.77, 0.38)		-0.11 (-0.45, 0.23)	
p-value [3]		0.500		0.535	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	93	
Mean (StdDev)	2.5 (1.37)	1.9 (1.04)	2.3 (1.14)	2.0 (1.24)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-0.26 (0.307)	-0.90 (0.220)	-0.42 (0.170)	-0.83 (0.133)	
95% CI [2]	-0.88, 0.36	-1.34, -0.46	-0.76, -0.08	-1.10, -0.57	
Difference (95% CI) in CFB [2]		-0.64 (-1.34, 0.05)		-0.41 (-0.78, -0.04)	
p-value [3]		0.069		0.028	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	2.5 (0.92)	1.9 (1.05)	2.4 (1.23)	2.1 (1.30)	
Median	3.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	-0.39 (0.283)	-0.95 (0.199)	-0.40 (0.190)	-0.85 (0.146)	
95% CI [2]	-0.96, 0.18	-1.35, -0.55	-0.77, -0.02	-1.14, -0.57	
Difference (95% CI) in CFB [2]		-0.56 (-1.20, 0.07)		-0.46 (-0.86, -0.06)	
p-value [3]		0.079		0.026	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	88	
Mean (StdDev)	2.3 (1.31)	1.7 (1.01)	2.3 (1.14)	2.0 (1.24)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	16	32	46	86	
LS Mean (StdErr) [2]	-0.38 (0.272)	-1.01 (0.202)	-0.50 (0.182)	-0.95 (0.143)	
95% CI [2]	-0.93, 0.17	-1.41, -0.60	-0.86, -0.14	-1.24, -0.67	
Difference (95% CI) in CFB [2]		-0.63 (-1.24, -0.01)		-0.46 (-0.85, -0.06)	
p-value [3]		0.045		0.024	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	2.7 (0.96)	1.7 (1.09)	2.4 (1.21)	1.9 (1.38)	
Median	3.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	-0.05 (0.290)	-1.06 (0.198)	-0.44 (0.193)	-1.07 (0.151)	
95% CI [2]	-0.63, 0.54	-1.46, -0.66	-0.82, -0.05	-1.37, -0.77	
Difference (95% CI) in CFB [2]		-1.01 (-1.67, -0.36)		-0.63 (-1.05, -0.21)	
p-value [3]		0.003		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	2.5 (1.15)	1.9 (1.04)	2.2 (1.35)	1.8 (1.38)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	-0.33 (0.311)	-0.83 (0.217)	-0.44 (0.191)	-0.95 (0.149)	
95% CI [2]	-0.96, 0.30	-1.26, -0.39	-0.82, -0.06	-1.25, -0.66	
Difference (95% CI) in CFB [2]		-0.50 (-1.19, 0.20)		-0.51 (-0.92, -0.11)	
Hedges'G (95% CI) in CFB		-0.39 (-1.04, 0.22)		-0.38 (-0.75, -0.02)	
p-value [3]		0.158		0.014	
					0.986

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	2.7 (0.95)	3.0 (0.80)	3.2 (0.90)	3.1 (1.02)	
Median	2.5	3.0	3.0	3.0	
Min, Max	1, 4	2, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	2.3 (1.13)	2.3 (0.85)	2.7 (0.94)	2.3 (1.17)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	-0.41 (0.239)	-0.76 (0.161)	-0.40 (0.154)	-0.68 (0.125)	
95% CI [2]	-0.89, 0.07	-1.08, -0.44	-0.71, -0.10	-0.93, -0.43	
Difference (95% CI) in CFB [2]		-0.35 (-0.88, 0.19)		-0.28 (-0.61, 0.06)	
p-value [3]		0.196		0.103	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	93	
Mean (StdDev)	2.4 (1.23)	1.9 (0.95)	2.5 (1.05)	2.1 (1.25)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-0.20 (0.308)	-1.05 (0.221)	-0.58 (0.176)	-0.85 (0.137)	
95% CI [2]	-0.81, 0.42	-1.49, -0.60	-0.93, -0.23	-1.13, -0.58	
Difference (95% CI) in CFB [2]		-0.85 (-1.55, -0.16)		-0.28 (-0.66, 0.10)	
p-value [3]		0.018		0.151	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	2.3 (1.29)	1.7 (0.86)	2.5 (1.12)	2.2 (1.22)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	-0.56 (0.291)	-1.37 (0.204)	-0.60 (0.181)	-0.89 (0.139)	
95% CI [2]	-1.15, 0.03	-1.78, -0.96	-0.96, -0.24	-1.16, -0.61	
Difference (95% CI) in CFB [2]		-0.81 (-1.46, -0.16)		-0.29 (-0.68, 0.09)	
p-value [3]		0.016		0.137	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	89	
Mean (StdDev)	2.1 (1.30)	1.8 (0.83)	2.5 (1.28)	2.2 (1.30)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	16	32	46	87	
LS Mean (StdErr) [2]	-0.70 (0.262)	-1.38 (0.195)	-0.53 (0.199)	-0.83 (0.156)	
95% CI [2]	-1.23, -0.17	-1.77, -0.99	-0.92, -0.14	-1.14, -0.52	
Difference (95% CI) in CFB [2]		-0.68 (-1.27, -0.09)		-0.30 (-0.73, 0.13)	
p-value [3]		0.025		0.176	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	2.4 (1.18)	1.6 (0.97)	2.6 (1.14)	2.1 (1.35)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	-0.42 (0.309)	-1.52 (0.210)	-0.42 (0.192)	-0.88 (0.150)	
95% CI [2]	-1.05, 0.20	-1.94, -1.09	-0.80, -0.04	-1.17, -0.58	
Difference (95% CI) in CFB [2]		-1.10 (-1.79, -0.40)		-0.46 (-0.88, -0.04)	
p-value [3]		0.003		0.032	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	2.4 (1.41)	1.9 (1.01)	2.3 (1.31)	2.0 (1.33)	
Median	2.5	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	-0.35 (0.312)	-1.14 (0.217)	-0.62 (0.202)	-0.95 (0.158)	
95% CI [2]	-0.98, 0.28	-1.58, -0.70	-1.02, -0.22	-1.27, -0.64	
Difference (95% CI) in CFB [2]		-0.79 (-1.49, -0.09)		-0.34 (-0.77, 0.09)	
Hedges'G (95% CI) in CFB		-0.62 (-1.29, -0.01)		-0.23 (-0.60, 0.13)	
p-value [3]		0.028		0.122	
					0.270

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	1.4 (1.46)	1.1 (1.23)	2.4 (1.43)	2.1 (1.46)	
Median	1.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	1.4 (1.36)	0.9 (1.13)	2.1 (1.42)	1.6 (1.43)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	0.14 (0.331)	-0.22 (0.223)	-0.02 (0.178)	-0.13 (0.144)	
95% CI [2]	-0.53, 0.80	-0.67, 0.23	-0.37, 0.33	-0.41, 0.16	
Difference (95% CI) in CFB [2]		-0.36 (-1.10, 0.38)		-0.11 (-0.50, 0.28)	
p-value [3]		0.338		0.572	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	93	
Mean (StdDev)	1.4 (1.32)	0.9 (1.08)	2.1 (1.38)	1.5 (1.43)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-0.14 (0.380)	-0.40 (0.273)	-0.02 (0.196)	-0.33 (0.153)	
95% CI [2]	-0.90, 0.63	-0.95, 0.15	-0.41, 0.37	-0.63, -0.03	
Difference (95% CI) in CFB [2]		-0.26 (-1.12, 0.60)		-0.31 (-0.73, 0.12)	
p-value [3]		0.539		0.154	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	1.6 (1.35)	0.8 (1.00)	1.9 (1.27)	1.7 (1.43)	
Median	1.0	0.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	0.26 (0.346)	-0.34 (0.243)	-0.31 (0.198)	-0.23 (0.152)	
95% CI [2]	-0.44, 0.95	-0.83, 0.15	-0.70, 0.08	-0.53, 0.07	
Difference (95% CI) in CFB [2]		-0.60 (-1.37, 0.18)		0.08 (-0.34, 0.50)	
p-value [3]		0.126		0.720	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	89	
Mean (StdDev)	1.6 (1.28)	0.8 (1.02)	1.8 (1.39)	1.6 (1.42)	
Median	2.0	0.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	16	32	46	87	
LS Mean (StdErr) [2]	0.18 (0.406)	-0.28 (0.301)	-0.28 (0.203)	-0.29 (0.159)	
95% CI [2]	-0.64, 1.00	-0.89, 0.33	-0.68, 0.12	-0.61, 0.02	
Difference (95% CI) in CFB [2]		-0.46 (-1.37, 0.45)		-0.02 (-0.46, 0.43)	
p-value [3]		0.314		0.946	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	1.6 (1.59)	0.7 (0.96)	1.9 (1.41)	1.6 (1.36)	
Median	1.0	0.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	0.27 (0.413)	-0.36 (0.281)	-0.34 (0.215)	-0.40 (0.168)	
95% CI [2]	-0.56, 1.11	-0.93, 0.21	-0.76, 0.09	-0.73, -0.07	
Difference (95% CI) in CFB [2]		-0.63 (-1.56, 0.30)		-0.06 (-0.53, 0.40)	
p-value [3]		0.177		0.792	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	1.6 (1.41)	0.9 (0.92)	2.0 (1.51)	1.4 (1.42)	
Median	1.5	1.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	0.17 (0.374)	-0.33 (0.261)	0.03 (0.224)	-0.28 (0.175)	
95% CI [2]	-0.59, 0.92	-0.85, 0.20	-0.41, 0.47	-0.63, 0.07	
Difference (95% CI) in CFB [2]		-0.50 (-1.33, 0.34)		-0.31 (-0.79, 0.17)	
Hedges'G (95% CI) in CFB		-0.33 (-0.97, 0.29)		-0.20 (-0.56, 0.17)	
p-value [3]		0.239		0.199	
					0.644

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	1.2 (0.91)	1.3 (1.16)	1.8 (1.31)	1.8 (1.34)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	1.5 (1.03)	1.1 (1.00)	1.5 (1.14)	1.4 (1.31)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	0.14 (0.240)	-0.24 (0.161)	-0.44 (0.131)	-0.55 (0.106)	
95% CI [2]	-0.34, 0.63	-0.57, 0.08	-0.70, -0.18	-0.76, -0.34	
Difference (95% CI) in CFB [2]		-0.38 (-0.92, 0.15)		-0.11 (-0.39, 0.18)	
p-value [3]		0.156		0.457	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	93	
Mean (StdDev)	1.1 (1.05)	0.9 (0.91)	1.6 (1.20)	1.1 (1.24)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-0.22 (0.274)	-0.43 (0.196)	-0.34 (0.184)	-0.84 (0.144)	
95% CI [2]	-0.78, 0.33	-0.83, -0.03	-0.70, 0.03	-1.13, -0.56	
Difference (95% CI) in CFB [2]		-0.21 (-0.83, 0.41)		-0.51 (-0.90, -0.11)	
p-value [3]		0.506		0.013	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	1.1 (1.06)	0.7 (0.81)	1.7 (1.21)	1.2 (1.25)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	-0.24 (0.269)	-0.55 (0.189)	-0.25 (0.203)	-0.77 (0.156)	
95% CI [2]	-0.78, 0.30	-0.93, -0.17	-0.65, 0.15	-1.08, -0.47	
Difference (95% CI) in CFB [2]		-0.32 (-0.92, 0.29)		-0.53 (-0.96, -0.09)	
p-value [3]		0.297		0.017	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	89	
Mean (StdDev)	1.4 (1.17)	0.6 (0.90)	1.5 (1.16)	1.1 (1.24)	
Median	1.0	0.0	1.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	16	32	46	87	
LS Mean (StdErr) [2]	0.01 (0.275)	-0.69 (0.204)	-0.46 (0.180)	-0.83 (0.142)	
95% CI [2]	-0.54, 0.57	-1.10, -0.28	-0.81, -0.10	-1.11, -0.55	
Difference (95% CI) in CFB [2]		-0.70 (-1.32, -0.08)		-0.37 (-0.77, 0.02)	
p-value [3]		0.027		0.062	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	1.3 (1.23)	0.8 (0.94)	1.5 (1.16)	1.2 (1.25)	
Median	1.0	0.0	1.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	-0.03 (0.294)	-0.60 (0.200)	-0.36 (0.179)	-0.76 (0.140)	
95% CI [2]	-0.62, 0.57	-1.00, -0.19	-0.71, -0.01	-1.03, -0.48	
Difference (95% CI) in CFB [2]		-0.57 (-1.23, 0.09)		-0.40 (-0.79, -0.01)	
p-value [3]		0.090		0.046	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	1.0 (1.10)	0.8 (0.96)	1.4 (1.12)	1.1 (1.19)	
Median	1.0	0.0	1.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	-0.35 (0.289)	-0.64 (0.202)	-0.40 (0.184)	-0.71 (0.144)	
95% CI [2]	-0.94, 0.23	-1.05, -0.23	-0.77, -0.04	-0.99, -0.42	
Difference (95% CI) in CFB [2]		-0.28 (-0.93, 0.36)		-0.30 (-0.70, 0.09)	
Hedges'G (95% CI) in CFB		-0.24 (-0.88, 0.37)		-0.23 (-0.60, 0.13)	
p-value [3]		0.381		0.129	
					0.979

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	0.8 (0.91)	1.0 (1.18)	1.3 (1.35)	1.5 (1.53)	
Median	0.5	1.0	1.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	1.3 (1.34)	0.9 (1.07)	1.1 (1.34)	1.3 (1.43)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	0.16 (0.287)	-0.03 (0.193)	-0.07 (0.161)	-0.22 (0.130)	
95% CI [2]	-0.42, 0.74	-0.42, 0.35	-0.39, 0.25	-0.48, 0.03	
Difference (95% CI) in CFB [2]		-0.19 (-0.84, 0.45)		-0.16 (-0.51, 0.19)	
p-value [3]		0.548		0.378	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	93	
Mean (StdDev)	0.7 (0.99)	0.7 (0.91)	1.1 (1.24)	1.0 (1.28)	
Median	0.0	0.0	1.0	0.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-0.15 (0.298)	-0.22 (0.214)	-0.13 (0.182)	-0.46 (0.142)	
95% CI [2]	-0.76, 0.45	-0.65, 0.21	-0.49, 0.23	-0.74, -0.18	
Difference (95% CI) in CFB [2]		-0.07 (-0.74, 0.61)		-0.33 (-0.73, 0.06)	
p-value [3]		0.839		0.097	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	0.8 (0.86)	0.7 (0.99)	1.5 (1.34)	1.1 (1.25)	
Median	1.0	0.0	1.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	-0.26 (0.303)	-0.34 (0.212)	0.05 (0.195)	-0.57 (0.149)	
95% CI [2]	-0.87, 0.35	-0.77, 0.09	-0.33, 0.44	-0.86, -0.27	
Difference (95% CI) in CFB [2]		-0.08 (-0.76, 0.60)		-0.62 (-1.03, -0.20)	
p-value [3]		0.810		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	89	
Mean (StdDev)	1.1 (1.20)	0.5 (0.84)	1.2 (1.28)	1.0 (1.28)	
Median	1.0	0.0	1.0	0.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C5D1 CFB					
n	16	32	46	87	
LS Mean (StdErr) [2]	0.12 (0.263)	-0.34 (0.195)	-0.11 (0.176)	-0.59 (0.138)	
95% CI [2]	-0.42, 0.65	-0.74, 0.05	-0.46, 0.24	-0.86, -0.32	
Difference (95% CI) in CFB [2]		-0.46 (-1.05, 0.13)		-0.48 (-0.86, -0.10)	
p-value [3]		0.126		0.015	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	1.0 (1.00)	0.8 (1.04)	1.2 (1.30)	0.9 (1.20)	
Median	1.0	0.0	1.0	0.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	0.02 (0.286)	-0.25 (0.195)	-0.09 (0.181)	-0.65 (0.141)	
95% CI [2]	-0.55, 0.60	-0.64, 0.14	-0.45, 0.27	-0.93, -0.37	
Difference (95% CI) in CFB [2]		-0.28 (-0.92, 0.37)		-0.56 (-0.96, -0.17)	
p-value [3]		0.390		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	0.9 (1.00)	0.8 (1.13)	1.2 (1.25)	0.9 (1.25)	
Median	1.0	0.0	1.0	0.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	0.14 (0.287)	-0.15 (0.200)	-0.08 (0.184)	-0.51 (0.144)	
95% CI [2]	-0.44, 0.72	-0.55, 0.25	-0.44, 0.29	-0.80, -0.23	
Difference (95% CI) in CFB [2]		-0.29 (-0.93, 0.36)		-0.44 (-0.83, -0.04)	
Hedges'G (95% CI) in CFB		-0.25 (-0.88, 0.37)		-0.33 (-0.70, 0.03)	
p-value [3]		0.373		0.029	
					0.694

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	2.1 (1.12)	1.5 (1.02)	1.9 (1.17)	2.0 (1.36)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	1.6 (1.31)	1.1 (0.98)	1.4 (1.25)	1.5 (1.33)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	-0.46 (0.237)	-0.55 (0.159)	-0.56 (0.175)	-0.67 (0.141)	
95% CI [2]	-0.93, 0.02	-0.87, -0.23	-0.91, -0.22	-0.95, -0.40	
Difference (95% CI) in CFB [2]		-0.09 (-0.62, 0.44)		-0.11 (-0.49, 0.27)	
p-value [3]		0.732		0.566	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	93	
Mean (StdDev)	1.6 (1.33)	0.9 (0.90)	1.5 (1.05)	1.4 (1.18)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-0.48 (0.250)	-0.58 (0.179)	-0.43 (0.168)	-0.66 (0.131)	
95% CI [2]	-0.98, 0.03	-0.94, -0.21	-0.76, -0.10	-0.92, -0.40	
Difference (95% CI) in CFB [2]		-0.10 (-0.66, 0.47)		-0.23 (-0.59, 0.14)	
p-value [3]		0.730		0.219	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	1.3 (1.28)	1.0 (0.89)	1.6 (1.24)	1.4 (1.29)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	-0.79 (0.289)	-0.66 (0.203)	-0.28 (0.202)	-0.70 (0.155)	
95% CI [2]	-1.37, -0.21	-1.07, -0.25	-0.68, 0.12	-1.01, -0.39	
Difference (95% CI) in CFB [2]		0.13 (-0.52, 0.78)		-0.42 (-0.85, 0.01)	
p-value [3]		0.688		0.055	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	89	
Mean (StdDev)	1.4 (1.42)	0.8 (0.87)	1.4 (1.28)	1.2 (1.26)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	16	32	46	87	
LS Mean (StdErr) [2]	-0.58 (0.273)	-0.62 (0.202)	-0.34 (0.187)	-0.83 (0.146)	
95% CI [2]	-1.13, -0.03	-1.03, -0.21	-0.71, 0.03	-1.12, -0.54	
Difference (95% CI) in CFB [2]		-0.05 (-0.66, 0.57)		-0.49 (-0.90, -0.09)	
p-value [3]		0.883		0.017	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	1.7 (1.40)	0.8 (0.82)	1.5 (1.27)	1.1 (1.19)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	-0.30 (0.266)	-0.79 (0.181)	-0.36 (0.197)	-1.12 (0.154)	
95% CI [2]	-0.84, 0.23	-1.15, -0.42	-0.75, 0.03	-1.43, -0.82	
Difference (95% CI) in CFB [2]		-0.49 (-1.08, 0.11)		-0.77 (-1.19, -0.34)	
p-value [3]		0.107		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	1.7 (1.40)	0.8 (0.87)	1.5 (1.36)	1.2 (1.31)	
Median	2.0	1.0	1.5	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	-0.31 (0.274)	-0.73 (0.191)	-0.24 (0.228)	-0.76 (0.178)	
95% CI [2]	-0.86, 0.24	-1.11, -0.34	-0.69, 0.21	-1.11, -0.41	
Difference (95% CI) in CFB [2]		-0.41 (-1.03, 0.20)		-0.52 (-1.01, -0.03)	
Hedges'G (95% CI) in CFB		-0.37 (-1.02, 0.24)		-0.32 (-0.69, 0.04)	
p-value [3]		0.180		0.036	
					0.797

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	2.0 (0.89)	2.1 (1.18)	2.4 (1.05)	2.3 (1.29)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	1.6 (1.15)	1.4 (0.99)	1.7 (1.13)	1.7 (1.38)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	-0.26 (0.237)	-0.69 (0.159)	-0.54 (0.171)	-0.53 (0.138)	
95% CI [2]	-0.74, 0.21	-1.01, -0.37	-0.87, -0.20	-0.80, -0.25	
Difference (95% CI) in CFB [2]		-0.43 (-0.96, 0.10)		0.01 (-0.36, 0.38)	
p-value [3]		0.110		0.956	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	93	
Mean (StdDev)	1.6 (1.23)	1.4 (1.10)	1.8 (1.11)	1.4 (1.14)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-0.38 (0.264)	-0.71 (0.189)	-0.50 (0.186)	-0.79 (0.145)	
95% CI [2]	-0.91, 0.15	-1.09, -0.33	-0.87, -0.13	-1.08, -0.50	
Difference (95% CI) in CFB [2]		-0.34 (-0.93, 0.26)		-0.29 (-0.69, 0.11)	
p-value [3]		0.264		0.153	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	92	
Mean (StdDev)	1.5 (1.06)	1.4 (1.13)	1.8 (1.18)	1.4 (1.32)	
Median	2.0	1.5	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	14	34	43	90	
LS Mean (StdErr) [2]	-0.51 (0.284)	-0.77 (0.199)	-0.59 (0.203)	-0.94 (0.155)	
95% CI [2]	-1.09, 0.06	-1.17, -0.37	-0.99, -0.18	-1.24, -0.63	
Difference (95% CI) in CFB [2]		-0.26 (-0.89, 0.38)		-0.35 (-0.78, 0.08)	
p-value [3]		0.417		0.109	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	89	
Mean (StdDev)	1.5 (1.33)	1.1 (0.89)	1.6 (1.33)	1.4 (1.31)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	16	32	46	87	
LS Mean (StdErr) [2]	-0.53 (0.274)	-1.05 (0.203)	-0.69 (0.209)	-0.85 (0.164)	
95% CI [2]	-1.08, 0.02	-1.46, -0.64	-1.11, -0.28	-1.18, -0.53	
Difference (95% CI) in CFB [2]		-0.52 (-1.13, 0.10)		-0.16 (-0.61, 0.30)	
p-value [3]		0.099		0.492	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	1.7 (1.11)	1.2 (1.05)	1.6 (1.31)	1.3 (1.33)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	-0.39 (0.292)	-1.01 (0.199)	-0.59 (0.207)	-0.99 (0.162)	
95% CI [2]	-0.98, 0.20	-1.41, -0.60	-1.00, -0.18	-1.31, -0.67	
Difference (95% CI) in CFB [2]		-0.61 (-1.27, 0.04)		-0.40 (-0.85, 0.06)	
p-value [3]		0.066		0.085	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	1.5 (1.26)	1.2 (1.04)	1.5 (1.22)	1.3 (1.32)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	-0.62 (0.307)	-1.06 (0.214)	-0.58 (0.209)	-0.66 (0.163)	
95% CI [2]	-1.23, 0.00	-1.49, -0.63	-1.00, -0.17	-0.98, -0.34	
Difference (95% CI) in CFB [2]		-0.44 (-1.13, 0.24)		-0.08 (-0.52, 0.37)	
Hedges'G (95% CI) in CFB		-0.35 (-1.00, 0.26)		-0.05 (-0.42, 0.31)	
p-value [3]		0.202		0.733	
					0.375

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	2.4 (0.81)	2.5 (0.90)	2.7 (1.20)	2.6 (1.20)	
Median	2.5	3.0	3.0	3.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	2.3 (1.13)	2.1 (1.03)	2.3 (1.12)	2.2 (1.23)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	-0.13 (0.208)	-0.41 (0.140)	-0.35 (0.157)	-0.50 (0.127)	
95% CI [2]	-0.55, 0.29	-0.69, -0.13	-0.66, -0.04	-0.75, -0.25	
Difference (95% CI) in CFB [2]		-0.28 (-0.75, 0.18)		-0.16 (-0.50, 0.19)	
p-value [3]		0.225		0.369	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	94	
Mean (StdDev)	2.3 (1.21)	1.9 (0.92)	2.2 (1.13)	2.1 (1.22)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	16	33	48	92	
LS Mean (StdErr) [2]	-0.19 (0.237)	-0.57 (0.170)	-0.43 (0.167)	-0.52 (0.131)	
95% CI [2]	-0.67, 0.29	-0.91, -0.22	-0.76, -0.10	-0.78, -0.26	
Difference (95% CI) in CFB [2]		-0.38 (-0.91, 0.16)		-0.09 (-0.45, 0.27)	
p-value [3]		0.164		0.626	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	2.3 (1.11)	2.1 (1.04)	2.3 (1.15)	1.9 (1.21)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	-0.06 (0.259)	-0.37 (0.182)	-0.35 (0.199)	-0.73 (0.152)	
95% CI [2]	-0.58, 0.46	-0.74, -0.01	-0.74, 0.05	-1.03, -0.43	
Difference (95% CI) in CFB [2]		-0.31 (-0.89, 0.27)		-0.38 (-0.81, 0.04)	
p-value [3]		0.285		0.075	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	89	
Mean (StdDev)	2.1 (1.22)	1.9 (0.95)	2.3 (1.08)	2.0 (1.22)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	16	32	46	87	
LS Mean (StdErr) [2]	-0.47 (0.261)	-0.82 (0.194)	-0.33 (0.200)	-0.62 (0.157)	
95% CI [2]	-0.99, 0.06	-1.21, -0.43	-0.72, 0.07	-0.93, -0.31	
Difference (95% CI) in CFB [2]		-0.35 (-0.94, 0.24)		-0.29 (-0.72, 0.15)	
p-value [3]		0.234		0.191	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	2.2 (1.32)	1.8 (1.03)	2.3 (1.20)	1.7 (1.20)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	-0.11 (0.264)	-0.70 (0.180)	-0.31 (0.208)	-0.82 (0.163)	
95% CI [2]	-0.65, 0.42	-1.06, -0.34	-0.72, 0.10	-1.14, -0.50	
Difference (95% CI) in CFB [2]		-0.59 (-1.18, 0.01)		-0.50 (-0.96, -0.05)	
p-value [3]		0.052		0.029	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	2.3 (1.20)	1.8 (0.89)	2.2 (1.26)	1.8 (1.24)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	-0.16 (0.229)	-0.76 (0.160)	-0.27 (0.211)	-0.71 (0.165)	
95% CI [2]	-0.62, 0.30	-1.08, -0.44	-0.69, 0.15	-1.04, -0.39	
Difference (95% CI) in CFB [2]		-0.60 (-1.11, -0.09)		-0.44 (-0.89, 0.01)	
Hedges'G (95% CI) in CFB		-0.64 (-1.31, -0.03)		-0.29 (-0.66, 0.07)	
p-value [3]		0.023		0.055	
					0.661

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	2.0 (1.55)	1.8 (1.06)	2.2 (1.32)	2.1 (1.39)	
Median	2.0	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	1.8 (1.39)	1.4 (0.99)	1.9 (1.27)	1.7 (1.42)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	-0.00 (0.249)	-0.25 (0.168)	-0.32 (0.157)	-0.46 (0.127)	
95% CI [2]	-0.50, 0.50	-0.59, 0.08	-0.63, -0.01	-0.71, -0.21	
Difference (95% CI) in CFB [2]		-0.25 (-0.81, 0.31)		-0.14 (-0.48, 0.20)	
p-value [3]		0.373		0.411	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	49	94	
Mean (StdDev)	1.6 (1.42)	1.2 (0.96)	1.7 (1.22)	1.5 (1.32)	
Median	1.0	1.0	2.0	1.5	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C3D1 CFB					
n	16	33	47	92	
LS Mean (StdErr) [2]	-0.26 (0.271)	-0.40 (0.195)	-0.51 (0.167)	-0.57 (0.130)	
95% CI [2]	-0.81, 0.29	-0.79, -0.01	-0.84, -0.19	-0.83, -0.31	
Difference (95% CI) in CFB [2]		-0.14 (-0.75, 0.47)		-0.05 (-0.41, 0.31)	
p-value [3]		0.650		0.766	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	1.7 (1.50)	1.4 (1.05)	1.7 (1.32)	1.5 (1.38)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	-0.14 (0.270)	-0.30 (0.189)	-0.59 (0.203)	-0.72 (0.155)	
95% CI [2]	-0.69, 0.40	-0.68, 0.08	-0.99, -0.18	-1.03, -0.41	
Difference (95% CI) in CFB [2]		-0.16 (-0.76, 0.45)		-0.13 (-0.56, 0.30)	
p-value [3]		0.605		0.542	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	89	
Mean (StdDev)	1.5 (1.37)	1.0 (0.97)	1.7 (1.33)	1.4 (1.32)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	16	32	46	87	
LS Mean (StdErr) [2]	-0.34 (0.310)	-0.55 (0.230)	-0.54 (0.202)	-0.87 (0.159)	
95% CI [2]	-0.97, 0.28	-1.01, -0.09	-0.94, -0.14	-1.19, -0.56	
Difference (95% CI) in CFB [2]		-0.20 (-0.90, 0.49)		-0.34 (-0.77, 0.10)	
p-value [3]		0.558		0.133	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	1.9 (1.46)	1.2 (1.07)	1.9 (1.40)	1.3 (1.27)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	-0.01 (0.299)	-0.60 (0.203)	-0.33 (0.203)	-0.85 (0.158)	
95% CI [2]	-0.62, 0.59	-1.01, -0.19	-0.73, 0.07	-1.16, -0.54	
Difference (95% CI) in CFB [2]		-0.59 (-1.26, 0.09)		-0.52 (-0.96, -0.08)	
p-value [3]		0.085		0.020	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	1.7 (1.45)	1.1 (1.05)	1.8 (1.35)	1.3 (1.40)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	-0.29 (0.321)	-0.53 (0.223)	-0.38 (0.187)	-0.80 (0.146)	
95% CI [2]	-0.94, 0.36	-0.98, -0.08	-0.75, -0.01	-1.09, -0.51	
Difference (95% CI) in CFB [2]		-0.24 (-0.96, 0.48)		-0.42 (-0.82, -0.02)	
Hedges'G (95% CI) in CFB		-0.19 (-0.82, 0.43)		-0.31 (-0.69, 0.05)	
p-value [3]		0.501		0.039	
					0.626

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	52	98	
Mean (StdDev)	2.2 (1.11)	2.1 (1.13)	2.4 (1.02)	2.5 (1.11)	
Median	2.0	2.0	2.5	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	1.9 (1.06)	1.6 (0.91)	1.8 (1.10)	1.9 (1.22)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C2D1 CFB					
n	15	36	51	96	
LS Mean (StdErr) [2]	-0.12 (0.203)	-0.60 (0.137)	-0.55 (0.181)	-0.66 (0.147)	
95% CI [2]	-0.53, 0.29	-0.88, -0.33	-0.91, -0.20	-0.95, -0.37	
Difference (95% CI) in CFB [2]		-0.48 (-0.93, -0.02)		-0.11 (-0.50, 0.29)	
p-value [3]		0.039		0.595	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	33	50	94	
Mean (StdDev)	1.9 (1.30)	1.5 (0.94)	1.9 (1.07)	1.7 (1.10)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	16	32	48	92	
LS Mean (StdErr) [2]	-0.29 (0.344)	-0.68 (0.249)	-0.48 (0.174)	-0.79 (0.136)	
95% CI [2]	-0.99, 0.40	-1.18, -0.18	-0.82, -0.14	-1.05, -0.52	
Difference (95% CI) in CFB [2]		-0.38 (-1.17, 0.40)		-0.31 (-0.68, 0.07)	
p-value [3]		0.328		0.110	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	2.2 (1.21)	1.5 (1.08)	1.8 (1.08)	1.7 (1.18)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	14	34	43	91	
LS Mean (StdErr) [2]	0.09 (0.328)	-0.58 (0.230)	-0.69 (0.186)	-0.92 (0.142)	
95% CI [2]	-0.57, 0.76	-1.04, -0.12	-1.06, -0.33	-1.20, -0.64	
Difference (95% CI) in CFB [2]		-0.68 (-1.41, 0.06)		-0.22 (-0.62, 0.17)	
p-value [3]		0.070		0.263	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	89	
Mean (StdDev)	1.6 (1.32)	1.2 (0.95)	1.8 (1.14)	1.6 (1.21)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	16	32	46	87	
LS Mean (StdErr) [2]	-0.68 (0.364)	-0.97 (0.270)	-0.61 (0.193)	-0.97 (0.151)	
95% CI [2]	-1.41, 0.06	-1.52, -0.43	-0.99, -0.23	-1.27, -0.67	
Difference (95% CI) in CFB [2]		-0.29 (-1.11, 0.53)		-0.36 (-0.78, 0.06)	
p-value [3]		0.476		0.092	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	1.8 (1.01)	1.4 (1.05)	1.9 (1.23)	1.5 (1.19)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	14	34	46	89	
LS Mean (StdErr) [2]	-0.35 (0.310)	-0.95 (0.211)	-0.54 (0.200)	-1.02 (0.156)	
95% CI [2]	-0.98, 0.27	-1.37, -0.52	-0.93, -0.14	-1.32, -0.71	
Difference (95% CI) in CFB [2]		-0.59 (-1.29, 0.10)		-0.48 (-0.91, -0.04)	
p-value [3]		0.092		0.031	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	2.0 (1.21)	1.3 (0.99)	1.7 (1.31)	1.6 (1.36)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	15	34	45	87	
LS Mean (StdErr) [2]	-0.15 (0.359)	-0.92 (0.250)	-0.53 (0.232)	-0.92 (0.181)	
95% CI [2]	-0.87, 0.58	-1.43, -0.42	-0.99, -0.07	-1.27, -0.56	
Difference (95% CI) in CFB [2]		-0.78 (-1.58, 0.03)		-0.38 (-0.88, 0.11)	
Hedges'G (95% CI) in CFB		-0.53 (-1.19, 0.08)		-0.23 (-0.60, 0.13)	
p-value [3]		0.058		0.127	
					0.401

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	51	98	
Mean (StdDev)	1.8 (1.47)	1.8 (1.12)	2.1 (1.19)	2.3 (1.19)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	1.6 (1.31)	1.6 (1.07)	1.9 (1.18)	1.8 (1.24)	
Median	1.5	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	15	36	50	96	
LS Mean (StdErr) [2]	-0.08 (0.244)	-0.26 (0.164)	-0.17 (0.173)	-0.49 (0.140)	
95% CI [2]	-0.57, 0.41	-0.59, 0.07	-0.51, 0.18	-0.77, -0.22	
Difference (95% CI) in CFB [2]		-0.18 (-0.73, 0.36)		-0.33 (-0.70, 0.05)	
p-value [3]		0.507		0.087	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	94	
Mean (StdDev)	1.7 (1.26)	1.3 (1.12)	1.8 (1.18)	1.6 (1.11)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	16	33	47	92	
LS Mean (StdErr) [2]	-0.00 (0.278)	-0.50 (0.199)	-0.21 (0.163)	-0.60 (0.127)	
95% CI [2]	-0.56, 0.56	-0.90, -0.10	-0.53, 0.11	-0.85, -0.35	
Difference (95% CI) in CFB [2]		-0.50 (-1.13, 0.13)		-0.39 (-0.74, -0.04)	
p-value [3]		0.118		0.031	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	1.5 (1.36)	1.3 (1.17)	1.8 (1.20)	1.7 (1.26)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	14	34	42	91	
LS Mean (StdErr) [2]	-0.04 (0.268)	-0.52 (0.188)	-0.28 (0.205)	-0.70 (0.156)	
95% CI [2]	-0.58, 0.50	-0.90, -0.14	-0.69, 0.12	-1.01, -0.39	
Difference (95% CI) in CFB [2]		-0.48 (-1.08, 0.12)		-0.41 (-0.85, 0.02)	
p-value [3]		0.116		0.062	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	89	
Mean (StdDev)	1.5 (1.18)	1.3 (1.06)	1.7 (1.09)	1.5 (1.16)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	16	32	45	87	
LS Mean (StdErr) [2]	-0.27 (0.290)	-0.52 (0.215)	-0.27 (0.193)	-0.76 (0.151)	
95% CI [2]	-0.85, 0.32	-0.96, -0.09	-0.66, 0.11	-1.05, -0.46	
Difference (95% CI) in CFB [2]		-0.26 (-0.91, 0.39)		-0.48 (-0.90, -0.06)	
p-value [3]		0.429		0.025	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	1.7 (1.29)	1.2 (1.13)	1.7 (1.19)	1.5 (1.22)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	14	34	45	89	
LS Mean (StdErr) [2]	-0.11 (0.249)	-0.81 (0.170)	-0.26 (0.205)	-0.85 (0.159)	
95% CI [2]	-0.61, 0.40	-1.15, -0.47	-0.67, 0.14	-1.16, -0.53	
Difference (95% CI) in CFB [2]		-0.70 (-1.26, -0.14)		-0.58 (-1.03, -0.14)	
p-value [3]		0.015		0.011	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.2a
Change from Baseline in MC-QoL Individual Item Scores by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	1.6 (1.26)	1.3 (1.07)	1.7 (1.15)	1.6 (1.32)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	15	34	44	87	
LS Mean (StdErr) [2]	-0.14 (0.317)	-0.54 (0.221)	-0.11 (0.211)	-0.59 (0.164)	
95% CI [2]	-0.78, 0.50	-0.98, -0.09	-0.53, 0.31	-0.92, -0.26	
Difference (95% CI) in CFB [2]		-0.40 (-1.11, 0.31)		-0.48 (-0.93, -0.03)	
Hedges'G (95% CI) in CFB		-0.31 (-0.95, 0.30)		-0.32 (-0.70, 0.04)	
p-value [3]		0.262		0.036	
					0.869

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-sex-a.sas Date: 16:01/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	2.7 (1.26)	2.3 (1.14)	2.7 (1.09)	2.3 (1.13)	
Median	3.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	2.3 (1.03)	1.5 (0.93)	2.2 (1.08)	1.6 (0.97)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	-0.44 (0.237)	-0.74 (0.185)	-0.35 (0.177)	-0.54 (0.134)	
95% CI [2]	-0.91, 0.03	-1.10, -0.37	-0.70, 0.00	-0.81, -0.28	
Difference (95% CI) in CFB [2]		-0.30 (-0.81, 0.22)		-0.20 (-0.59, 0.19)	
p-value [3]		0.259		0.320	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	52	37	76	
Mean (StdDev)	2.1 (1.05)	1.4 (0.87)	2.0 (1.21)	1.6 (1.02)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	-0.58 (0.244)	-0.81 (0.193)	-0.57 (0.206)	-0.65 (0.152)	
95% CI [2]	-1.07, -0.10	-1.20, -0.43	-0.98, -0.16	-0.95, -0.34	
Difference (95% CI) in CFB [2]		-0.23 (-0.77, 0.30)		-0.08 (-0.53, 0.38)	
p-value [3]		0.392		0.739	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	2.3 (1.06)	1.3 (0.94)	2.1 (1.12)	1.5 (1.07)	
Median	2.0	1.0	2.0	1.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	-0.42 (0.278)	-1.10 (0.207)	-0.53 (0.220)	-0.83 (0.165)	
95% CI [2]	-0.98, 0.13	-1.51, -0.69	-0.96, -0.09	-1.15, -0.50	
Difference (95% CI) in CFB [2]		-0.68 (-1.25, -0.10)		-0.30 (-0.79, 0.18)	
p-value [3]		0.021		0.222	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	46	37	78	
Mean (StdDev)	2.3 (1.30)	1.2 (0.95)	2.2 (1.12)	1.4 (1.01)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	41	37	77	
LS Mean (StdErr) [2]	-0.41 (0.270)	-1.08 (0.224)	-0.40 (0.222)	-0.78 (0.165)	
95% CI [2]	-0.95, 0.13	-1.53, -0.63	-0.84, 0.04	-1.11, -0.45	
Difference (95% CI) in CFB [2]		-0.67 (-1.27, -0.08)		-0.38 (-0.87, 0.11)	
p-value [3]		0.028		0.126	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	2.0 (1.32)	1.4 (1.03)	2.2 (1.15)	1.5 (1.07)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	-0.77 (0.260)	-0.89 (0.200)	-0.39 (0.217)	-0.71 (0.161)	
95% CI [2]	-1.29, -0.25	-1.28, -0.49	-0.82, 0.04	-1.03, -0.40	
Difference (95% CI) in CFB [2]		-0.12 (-0.68, 0.45)		-0.33 (-0.81, 0.15)	
p-value [3]		0.684		0.177	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	2.2 (1.30)	1.2 (0.83)	2.2 (1.09)	1.4 (1.09)	
Median	3.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-0.60 (0.283)	-1.10 (0.222)	-0.26 (0.197)	-0.70 (0.146)	
95% CI [2]	-1.16, -0.03	-1.54, -0.65	-0.65, 0.14	-0.99, -0.41	
Difference (95% CI) in CFB [2]		-0.50 (-1.09, 0.09)		-0.44 (-0.88, -0.01)	
Hedges'G (95% CI) in CFB		-0.34 (-0.87, 0.16)		-0.35 (-0.76, 0.04)	
p-value [3]		0.095		0.046	
					0.854

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	2.7 (1.18)	2.0 (1.21)	2.3 (1.14)	2.1 (1.10)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	2.3 (1.22)	1.4 (1.12)	2.0 (1.10)	1.4 (0.86)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	-0.08 (0.266)	-0.42 (0.208)	-0.28 (0.185)	-0.62 (0.140)	
95% CI [2]	-0.61, 0.45	-0.84, -0.01	-0.64, 0.09	-0.90, -0.34	
Difference (95% CI) in CFB [2]		-0.35 (-0.93, 0.23)		-0.35 (-0.75, 0.06)	
p-value [3]		0.239		0.095	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	52	37	76	
Mean (StdDev)	2.2 (1.26)	1.3 (0.96)	2.0 (1.22)	1.5 (1.03)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	-0.39 (0.266)	-0.59 (0.210)	-0.31 (0.216)	-0.64 (0.160)	
95% CI [2]	-0.92, 0.14	-1.01, -0.17	-0.74, 0.12	-0.95, -0.32	
Difference (95% CI) in CFB [2]		-0.20 (-0.79, 0.38)		-0.32 (-0.80, 0.15)	
p-value [3]		0.495		0.182	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	2.2 (1.09)	1.2 (0.96)	2.0 (1.14)	1.4 (1.05)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	-0.33 (0.286)	-0.78 (0.213)	-0.13 (0.211)	-0.67 (0.157)	
95% CI [2]	-0.90, 0.24	-1.21, -0.36	-0.55, 0.29	-0.98, -0.36	
Difference (95% CI) in CFB [2]		-0.46 (-1.05, 0.13)		-0.54 (-1.00, -0.07)	
p-value [3]		0.128		0.024	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	46	37	78	
Mean (StdDev)	2.1 (1.44)	1.3 (0.93)	2.0 (1.19)	1.4 (1.03)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	41	37	77	
LS Mean (StdErr) [2]	-0.29 (0.290)	-0.56 (0.240)	-0.22 (0.216)	-0.62 (0.161)	
95% CI [2]	-0.87, 0.29	-1.04, -0.09	-0.65, 0.21	-0.94, -0.30	
Difference (95% CI) in CFB [2]		-0.28 (-0.92, 0.36)		-0.40 (-0.88, 0.08)	
p-value [3]		0.385		0.099	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	2.3 (1.21)	1.3 (0.93)	1.9 (1.18)	1.5 (1.15)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	0.01 (0.272)	-0.62 (0.208)	-0.25 (0.220)	-0.58 (0.163)	
95% CI [2]	-0.53, 0.56	-1.03, -0.20	-0.69, 0.18	-0.90, -0.25	
Difference (95% CI) in CFB [2]		-0.63 (-1.22, -0.04)		-0.32 (-0.81, 0.16)	
p-value [3]		0.037		0.190	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	2.0 (1.34)	1.2 (0.91)	2.1 (1.16)	1.5 (1.20)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-0.27 (0.301)	-0.62 (0.236)	-0.06 (0.222)	-0.50 (0.164)	
95% CI [2]	-0.87, 0.34	-1.10, -0.15	-0.50, 0.38	-0.83, -0.18	
Difference (95% CI) in CFB [2]		-0.36 (-0.98, 0.27)		-0.44 (-0.93, 0.04)	
Hedges'G (95% CI) in CFB		-0.23 (-0.75, 0.28)		-0.31 (-0.72, 0.08)	
p-value [3]		0.258		0.075	
					0.844

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	2.3 (1.02)	2.4 (1.03)	2.2 (1.22)	2.3 (1.14)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	2.1 (1.04)	1.7 (1.02)	2.0 (1.12)	1.9 (1.09)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	-0.29 (0.220)	-0.69 (0.172)	-0.09 (0.170)	-0.15 (0.129)	
95% CI [2]	-0.73, 0.15	-1.03, -0.35	-0.43, 0.24	-0.41, 0.10	
Difference (95% CI) in CFB [2]		-0.40 (-0.88, 0.08)		-0.06 (-0.44, 0.31)	
p-value [3]		0.103		0.743	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	52	37	76	
Mean (StdDev)	2.1 (0.91)	1.8 (1.11)	1.9 (1.07)	1.7 (1.10)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	-0.07 (0.262)	-0.38 (0.207)	-0.23 (0.195)	-0.49 (0.145)	
95% CI [2]	-0.59, 0.45	-0.79, 0.03	-0.62, 0.16	-0.78, -0.20	
Difference (95% CI) in CFB [2]		-0.31 (-0.88, 0.27)		-0.26 (-0.70, 0.17)	
p-value [3]		0.291		0.228	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	2.3 (1.10)	1.7 (0.92)	1.9 (1.13)	1.7 (1.09)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	-0.13 (0.285)	-0.62 (0.212)	-0.20 (0.206)	-0.54 (0.154)	
95% CI [2]	-0.70, 0.44	-1.04, -0.19	-0.61, 0.21	-0.84, -0.23	
Difference (95% CI) in CFB [2]		-0.49 (-1.08, 0.10)		-0.34 (-0.79, 0.12)	
p-value [3]		0.103		0.143	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	46	37	78	
Mean (StdDev)	1.9 (1.24)	1.7 (1.05)	2.0 (1.25)	1.7 (1.05)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	41	37	77	
LS Mean (StdErr) [2]	-0.43 (0.259)	-0.59 (0.214)	-0.12 (0.223)	-0.46 (0.165)	
95% CI [2]	-0.95, 0.09	-1.02, -0.16	-0.56, 0.32	-0.79, -0.14	
Difference (95% CI) in CFB [2]		-0.16 (-0.73, 0.41)		-0.34 (-0.83, 0.15)	
p-value [3]		0.571		0.169	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	2.0 (1.27)	1.5 (1.04)	1.8 (1.08)	1.7 (1.15)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	-0.12 (0.278)	-0.82 (0.213)	-0.33 (0.206)	-0.41 (0.152)	
95% CI [2]	-0.67, 0.44	-1.25, -0.40	-0.74, 0.08	-0.71, -0.11	
Difference (95% CI) in CFB [2]		-0.71 (-1.31, -0.10)		-0.08 (-0.53, 0.37)	
p-value [3]		0.023		0.729	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	1.8 (1.25)	1.5 (0.95)	1.9 (1.06)	1.7 (1.17)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-0.57 (0.293)	-1.03 (0.229)	-0.13 (0.226)	-0.35 (0.168)	
95% CI [2]	-1.15, 0.02	-1.49, -0.58	-0.58, 0.32	-0.68, -0.01	
Difference (95% CI) in CFB [2]		-0.47 (-1.07, 0.14)		-0.22 (-0.71, 0.28)	
Hedges'G (95% CI) in CFB		-0.31 (-0.83, 0.20)		-0.15 (-0.55, 0.25)	
p-value [3]		0.131		0.395	
					0.482

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	1.9 (1.24)	2.3 (1.27)	2.2 (1.19)	2.0 (1.20)	
Median	2.0	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	58	38	78	
Mean (StdDev)	1.6 (1.31)	1.5 (1.08)	1.8 (1.08)	1.4 (1.12)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	53	38	78	
LS Mean (StdErr) [2]	-0.33 (0.262)	-0.74 (0.211)	-0.28 (0.188)	-0.47 (0.143)	
95% CI [2]	-0.85, 0.19	-1.16, -0.32	-0.66, 0.09	-0.76, -0.19	
Difference (95% CI) in CFB [2]		-0.41 (-0.98, 0.15)		-0.19 (-0.60, 0.22)	
p-value [3]		0.152		0.365	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	52	37	76	
Mean (StdDev)	1.7 (1.35)	1.5 (1.15)	1.8 (1.27)	1.4 (1.13)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	-0.21 (0.292)	-0.66 (0.230)	-0.24 (0.211)	-0.56 (0.157)	
95% CI [2]	-0.79, 0.37	-1.12, -0.21	-0.66, 0.17	-0.87, -0.25	
Difference (95% CI) in CFB [2]		-0.46 (-1.10, 0.18)		-0.32 (-0.78, 0.15)	
p-value [3]		0.158		0.179	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	1.7 (1.32)	1.5 (1.16)	1.8 (1.16)	1.4 (1.19)	
Median	2.0	1.5	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	-0.56 (0.316)	-0.83 (0.236)	-0.27 (0.197)	-0.58 (0.147)	
95% CI [2]	-1.19, 0.08	-1.30, -0.36	-0.66, 0.12	-0.87, -0.29	
Difference (95% CI) in CFB [2]		-0.28 (-0.93, 0.38)		-0.31 (-0.74, 0.13)	
p-value [3]		0.402		0.164	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	46	37	78	
Mean (StdDev)	1.6 (1.15)	1.5 (1.22)	1.9 (1.06)	1.3 (1.12)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	41	37	77	
LS Mean (StdErr) [2]	-0.20 (0.281)	-0.76 (0.232)	-0.15 (0.223)	-0.68 (0.166)	
95% CI [2]	-0.77, 0.36	-1.23, -0.30	-0.59, 0.29	-1.00, -0.35	
Difference (95% CI) in CFB [2]		-0.56 (-1.18, 0.06)		-0.53 (-1.02, -0.03)	
p-value [3]		0.075		0.036	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	1.6 (1.26)	1.1 (0.99)	1.8 (1.15)	1.4 (1.19)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	-0.31 (0.270)	-1.09 (0.207)	-0.15 (0.214)	-0.42 (0.159)	
95% CI [2]	-0.85, 0.23	-1.50, -0.67	-0.58, 0.27	-0.73, -0.10	
Difference (95% CI) in CFB [2]		-0.78 (-1.37, -0.19)		-0.26 (-0.74, 0.21)	
p-value [3]		0.010		0.270	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	1.5 (1.08)	1.2 (1.17)	1.8 (1.09)	1.5 (1.23)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-0.09 (0.319)	-0.84 (0.250)	-0.17 (0.204)	-0.39 (0.151)	
95% CI [2]	-0.73, 0.55	-1.34, -0.34	-0.58, 0.23	-0.69, -0.09	
Difference (95% CI) in CFB [2]		-0.75 (-1.42, -0.09)		-0.22 (-0.67, 0.23)	
Hedges'G (95% CI) in CFB		-0.46 (-0.99, 0.05)		-0.17 (-0.57, 0.23)	
p-value [3]		0.027		0.344	
					0.180

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	3.0 (1.02)	3.1 (0.96)	3.3 (0.79)	3.2 (0.91)	
Median	3.0	3.0	3.0	3.0	
Min, Max	1, 4	1, 4	2, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	2.7 (1.04)	2.6 (1.12)	2.9 (0.88)	2.7 (1.05)	
Median	3.0	3.0	3.0	3.0	
Min, Max	1, 4	0, 4	1, 4	1, 4	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	-0.32 (0.215)	-0.60 (0.169)	-0.37 (0.159)	-0.45 (0.121)	
95% CI [2]	-0.75, 0.11	-0.94, -0.27	-0.69, -0.05	-0.69, -0.21	
Difference (95% CI) in CFB [2]		-0.28 (-0.75, 0.19)		-0.08 (-0.43, 0.27)	
p-value [3]		0.235		0.664	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	52	37	76	
Mean (StdDev)	2.6 (1.30)	2.4 (1.05)	2.7 (0.88)	2.4 (1.12)	
Median	3.0	2.0	3.0	2.5	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	-0.32 (0.240)	-0.77 (0.190)	-0.55 (0.188)	-0.66 (0.140)	
95% CI [2]	-0.80, 0.16	-1.15, -0.39	-0.93, -0.18	-0.94, -0.38	
Difference (95% CI) in CFB [2]		-0.46 (-0.98, 0.07)		-0.11 (-0.52, 0.31)	
p-value [3]		0.088		0.610	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	2.8 (1.20)	2.1 (1.09)	2.7 (1.07)	2.6 (1.11)	
Median	3.0	2.0	3.0	3.0	
Min, Max	1, 4	0, 4	1, 4	0, 4	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	-0.47 (0.239)	-1.05 (0.178)	-0.46 (0.211)	-0.48 (0.157)	
95% CI [2]	-0.95, 0.00	-1.41, -0.70	-0.87, -0.04	-0.80, -0.17	
Difference (95% CI) in CFB [2]		-0.58 (-1.07, -0.08)		-0.03 (-0.49, 0.44)	
p-value [3]		0.023		0.908	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	46	37	78	
Mean (StdDev)	2.6 (1.40)	2.2 (1.13)	2.8 (1.03)	2.4 (1.13)	
Median	3.0	2.0	3.0	2.5	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	41	37	77	
LS Mean (StdErr) [2]	-0.71 (0.255)	-1.00 (0.210)	-0.35 (0.207)	-0.66 (0.154)	
95% CI [2]	-1.22, -0.20	-1.42, -0.58	-0.76, 0.06	-0.96, -0.35	
Difference (95% CI) in CFB [2]		-0.29 (-0.85, 0.27)		-0.31 (-0.77, 0.15)	
p-value [3]		0.297		0.183	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	2.6 (1.26)	2.0 (1.12)	2.6 (0.99)	2.5 (1.15)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	-0.62 (0.257)	-1.20 (0.197)	-0.64 (0.208)	-0.64 (0.154)	
95% CI [2]	-1.13, -0.11	-1.59, -0.81	-1.05, -0.23	-0.94, -0.33	
Difference (95% CI) in CFB [2]		-0.58 (-1.14, -0.02)		0.00 (-0.46, 0.46)	
p-value [3]		0.043		0.993	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	2.4 (1.26)	2.1 (1.00)	2.7 (0.94)	2.5 (1.10)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-0.78 (0.261)	-1.13 (0.204)	-0.50 (0.205)	-0.58 (0.152)	
95% CI [2]	-1.30, -0.26	-1.54, -0.72	-0.91, -0.09	-0.88, -0.28	
Difference (95% CI) in CFB [2]		-0.35 (-0.89, 0.19)		-0.08 (-0.53, 0.37)	
Hedges'G (95% CI) in CFB		-0.26 (-0.78, 0.25)		-0.06 (-0.46, 0.34)	
p-value [3]		0.203		0.729	
					0.462

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	2.0 (1.17)	2.2 (1.09)	2.2 (1.07)	2.0 (1.16)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	2.1 (1.21)	1.7 (0.98)	1.8 (0.95)	1.8 (1.07)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	0.14 (0.228)	-0.48 (0.178)	-0.37 (0.145)	-0.17 (0.110)	
95% CI [2]	-0.31, 0.59	-0.83, -0.12	-0.65, -0.08	-0.38, 0.05	
Difference (95% CI) in CFB [2]		-0.62 (-1.11, -0.12)		0.20 (-0.12, 0.52)	
p-value [3]		0.016		0.218	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	52	37	76	
Mean (StdDev)	1.8 (1.21)	1.7 (0.88)	1.9 (1.00)	1.5 (1.08)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	-0.22 (0.239)	-0.70 (0.189)	-0.30 (0.194)	-0.39 (0.144)	
95% CI [2]	-0.70, 0.26	-1.07, -0.32	-0.68, 0.09	-0.67, -0.10	
Difference (95% CI) in CFB [2]		-0.48 (-1.00, 0.05)		-0.09 (-0.52, 0.34)	
p-value [3]		0.074		0.683	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	1.8 (1.24)	1.7 (0.94)	1.9 (1.18)	1.7 (1.27)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	-0.22 (0.285)	-0.48 (0.212)	-0.27 (0.199)	-0.32 (0.149)	
95% CI [2]	-0.79, 0.35	-0.90, -0.05	-0.66, 0.13	-0.62, -0.03	
Difference (95% CI) in CFB [2]		-0.26 (-0.85, 0.33)		-0.06 (-0.50, 0.38)	
p-value [3]		0.379		0.797	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	46	37	78	
Mean (StdDev)	2.0 (1.30)	1.7 (1.03)	1.8 (1.21)	1.6 (1.21)	
Median	2.0	2.0	1.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	41	37	77	
LS Mean (StdErr) [2]	-0.10 (0.232)	-0.34 (0.192)	-0.39 (0.198)	-0.38 (0.147)	
95% CI [2]	-0.56, 0.37	-0.73, 0.04	-0.78, 0.00	-0.67, -0.09	
Difference (95% CI) in CFB [2]		-0.25 (-0.76, 0.26)		0.00 (-0.43, 0.44)	
p-value [3]		0.337		0.986	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	2.0 (1.17)	1.5 (1.04)	1.8 (1.04)	1.6 (1.20)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	-0.22 (0.245)	-0.70 (0.188)	-0.33 (0.186)	-0.30 (0.138)	
95% CI [2]	-0.71, 0.27	-1.08, -0.33	-0.70, 0.04	-0.57, -0.03	
Difference (95% CI) in CFB [2]		-0.48 (-1.01, 0.06)		0.03 (-0.38, 0.44)	
p-value [3]		0.080		0.892	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	1.8 (1.12)	1.6 (1.05)	1.7 (1.10)	1.5 (1.15)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-0.13 (0.290)	-0.43 (0.227)	-0.44 (0.190)	-0.38 (0.141)	
95% CI [2]	-0.71, 0.45	-0.88, 0.03	-0.82, -0.07	-0.66, -0.11	
Difference (95% CI) in CFB [2]		-0.30 (-0.90, 0.31)		0.06 (-0.36, 0.48)	
Hedges'G (95% CI) in CFB		-0.20 (-0.72, 0.31)		0.05 (-0.35, 0.45)	
p-value [3]		0.328		0.784	
					0.325

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	2.5 (1.28)	2.7 (1.28)	2.8 (1.03)	2.8 (1.17)	
Median	3.0	3.0	3.0	3.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	58	38	78	
Mean (StdDev)	2.2 (1.29)	2.1 (1.14)	2.4 (0.86)	2.2 (1.15)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C2D1 CFB					
n	28	53	38	78	
LS Mean (StdErr) [2]	-0.21 (0.234)	-0.33 (0.188)	-0.34 (0.145)	-0.48 (0.110)	
95% CI [2]	-0.68, 0.25	-0.70, 0.05	-0.63, -0.05	-0.69, -0.26	
Difference (95% CI) in CFB [2]		-0.11 (-0.62, 0.40)		-0.14 (-0.46, 0.18)	
p-value [3]		0.659		0.401	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	52	37	76	
Mean (StdDev)	2.0 (1.25)	2.1 (1.29)	2.3 (1.00)	2.0 (1.19)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	-0.52 (0.285)	-0.57 (0.225)	-0.47 (0.180)	-0.62 (0.134)	
95% CI [2]	-1.09, 0.05	-1.02, -0.12	-0.83, -0.11	-0.88, -0.35	
Difference (95% CI) in CFB [2]		-0.05 (-0.68, 0.57)		-0.14 (-0.54, 0.25)	
p-value [3]		0.867		0.473	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	2.3 (1.29)	2.1 (1.18)	2.5 (1.02)	2.1 (1.25)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	-0.44 (0.338)	-0.75 (0.252)	-0.25 (0.193)	-0.47 (0.144)	
95% CI [2]	-1.11, 0.24	-1.25, -0.25	-0.63, 0.13	-0.76, -0.18	
Difference (95% CI) in CFB [2]		-0.31 (-1.01, 0.39)		-0.22 (-0.65, 0.20)	
p-value [3]		0.375		0.306	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	46	37	78	
Mean (StdDev)	2.2 (1.24)	2.1 (1.15)	2.6 (0.98)	2.2 (1.27)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C5D1 CFB					
n	25	41	37	77	
LS Mean (StdErr) [2]	-0.38 (0.248)	-0.57 (0.205)	-0.20 (0.199)	-0.52 (0.148)	
95% CI [2]	-0.88, 0.11	-0.98, -0.16	-0.59, 0.20	-0.82, -0.23	
Difference (95% CI) in CFB [2]		-0.19 (-0.73, 0.36)		-0.33 (-0.77, 0.11)	
p-value [3]		0.498		0.142	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	2.2 (1.40)	2.0 (1.22)	2.6 (0.98)	2.1 (1.21)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	-0.49 (0.302)	-0.74 (0.231)	-0.09 (0.193)	-0.47 (0.143)	
95% CI [2]	-1.09, 0.11	-1.20, -0.28	-0.48, 0.29	-0.76, -0.19	
Difference (95% CI) in CFB [2]		-0.25 (-0.91, 0.41)		-0.38 (-0.80, 0.05)	
p-value [3]		0.454		0.082	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	1.8 (1.34)	2.0 (1.16)	2.5 (0.96)	2.2 (1.21)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-0.50 (0.280)	-0.57 (0.219)	-0.28 (0.191)	-0.40 (0.142)	
95% CI [2]	-1.06, 0.06	-1.00, -0.13	-0.66, 0.10	-0.68, -0.12	
Difference (95% CI) in CFB [2]		-0.07 (-0.65, 0.52)		-0.12 (-0.54, 0.31)	
Hedges'G (95% CI) in CFB		-0.05 (-0.56, 0.47)		-0.10 (-0.50, 0.30)	
p-value [3]		0.824		0.583	
					0.852

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	2.2 (1.24)	2.6 (0.99)	2.3 (1.06)	2.6 (1.18)	
Median	2.0	3.0	2.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	30	59	38	78	
Mean (StdDev)	2.0 (1.30)	2.0 (1.06)	2.1 (1.11)	2.1 (1.19)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	27	54	38	78	
LS Mean (StdErr) [2]	-0.16 (0.202)	-0.62 (0.157)	-0.08 (0.155)	-0.43 (0.118)	
95% CI [2]	-0.57, 0.24	-0.93, -0.31	-0.38, 0.23	-0.66, -0.20	
Difference (95% CI) in CFB [2]		-0.46 (-0.90, -0.01)		-0.36 (-0.70, -0.02)	
p-value [3]		0.043		0.041	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	52	37	76	
Mean (StdDev)	2.2 (1.23)	1.8 (1.13)	1.9 (1.20)	1.9 (1.14)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	-0.01 (0.188)	-0.75 (0.149)	-0.23 (0.161)	-0.57 (0.120)	
95% CI [2]	-0.38, 0.37	-1.05, -0.46	-0.55, 0.09	-0.80, -0.33	
Difference (95% CI) in CFB [2]		-0.74 (-1.16, -0.33)		-0.34 (-0.69, 0.02)	
p-value [3]		<0.001		0.062	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	2.2 (1.27)	1.8 (1.12)	1.9 (1.16)	2.0 (1.18)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	0.10 (0.265)	-0.68 (0.197)	-0.34 (0.165)	-0.53 (0.123)	
95% CI [2]	-0.43, 0.63	-1.08, -0.29	-0.67, -0.01	-0.77, -0.28	
Difference (95% CI) in CFB [2]		-0.79 (-1.33, -0.24)		-0.19 (-0.55, 0.18)	
p-value [3]		0.006		0.310	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	46	37	78	
Mean (StdDev)	2.0 (1.29)	1.8 (0.99)	2.1 (1.21)	1.9 (1.22)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	41	37	77	
LS Mean (StdErr) [2]	-0.31 (0.260)	-0.75 (0.215)	-0.06 (0.174)	-0.58 (0.129)	
95% CI [2]	-0.83, 0.21	-1.18, -0.32	-0.41, 0.28	-0.84, -0.32	
Difference (95% CI) in CFB [2]		-0.44 (-1.01, 0.13)		-0.52 (-0.90, -0.13)	
p-value [3]		0.128		0.009	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	2.0 (1.41)	1.5 (1.08)	1.9 (1.10)	1.9 (1.27)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	-0.32 (0.261)	-1.06 (0.200)	-0.28 (0.175)	-0.57 (0.130)	
95% CI [2]	-0.84, 0.20	-1.46, -0.66	-0.63, 0.07	-0.83, -0.32	
Difference (95% CI) in CFB [2]		-0.74 (-1.31, -0.17)		-0.30 (-0.68, 0.09)	
p-value [3]		0.011		0.132	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	1.8 (1.40)	1.6 (1.11)	2.1 (1.04)	1.9 (1.26)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-0.23 (0.280)	-1.07 (0.219)	-0.13 (0.171)	-0.61 (0.126)	
95% CI [2]	-0.79, 0.33	-1.50, -0.63	-0.46, 0.21	-0.86, -0.36	
Difference (95% CI) in CFB [2]		-0.84 (-1.42, -0.26)		-0.49 (-0.86, -0.11)	
Hedges'G (95% CI) in CFB		-0.58 (-1.12, -0.08)		-0.45 (-0.86, -0.06)	
p-value [3]		0.005		0.012	
					0.293

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	2.0 (1.35)	1.7 (1.40)	2.0 (1.42)	2.4 (1.37)	
Median	2.0	1.0	2.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	1.5 (1.46)	1.2 (1.19)	1.8 (1.32)	1.9 (1.39)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	-0.47 (0.334)	-0.57 (0.261)	-0.16 (0.217)	-0.35 (0.164)	
95% CI [2]	-1.13, 0.20	-1.09, -0.05	-0.59, 0.27	-0.68, -0.03	
Difference (95% CI) in CFB [2]		-0.10 (-0.83, 0.63)		-0.20 (-0.68, 0.28)	
p-value [3]		0.783		0.415	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	51	37	76	
Mean (StdDev)	1.4 (1.25)	1.2 (1.19)	2.0 (1.34)	1.7 (1.39)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	-0.44 (0.344)	-0.31 (0.272)	-0.04 (0.230)	-0.61 (0.171)	
95% CI [2]	-1.13, 0.25	-0.85, 0.23	-0.49, 0.42	-0.95, -0.27	
Difference (95% CI) in CFB [2]		0.13 (-0.63, 0.89)		-0.57 (-1.08, -0.06)	
p-value [3]		0.735		0.028	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	1.5 (1.27)	1.1 (1.09)	2.0 (1.19)	1.7 (1.36)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	-0.56 (0.431)	-0.62 (0.321)	0.06 (0.225)	-0.57 (0.168)	
95% CI [2]	-1.42, 0.30	-1.26, 0.02	-0.38, 0.51	-0.90, -0.24	
Difference (95% CI) in CFB [2]		-0.06 (-0.95, 0.83)		-0.63 (-1.13, -0.14)	
p-value [3]		0.894		0.013	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	36	78	
Mean (StdDev)	1.6 (1.28)	0.9 (1.08)	2.0 (1.16)	1.6 (1.32)	
Median	1.0	1.0	2.0	1.5	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	42	36	77	
LS Mean (StdErr) [2]	-0.44 (0.361)	-0.79 (0.295)	0.05 (0.234)	-0.74 (0.173)	
95% CI [2]	-1.16, 0.28	-1.38, -0.20	-0.42, 0.51	-1.08, -0.39	
Difference (95% CI) in CFB [2]		-0.36 (-1.15, 0.43)		-0.78 (-1.30, -0.27)	
p-value [3]		0.369		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	1.8 (1.55)	0.9 (1.08)	1.9 (1.13)	1.7 (1.31)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	-0.35 (0.384)	-0.76 (0.294)	-0.07 (0.215)	-0.55 (0.160)	
95% CI [2]	-1.12, 0.42	-1.35, -0.18	-0.50, 0.36	-0.87, -0.24	
Difference (95% CI) in CFB [2]		-0.41 (-1.25, 0.43)		-0.48 (-0.96, -0.01)	
p-value [3]		0.331		0.046	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	1.3 (1.25)	1.0 (1.13)	1.8 (1.33)	1.6 (1.32)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-0.63 (0.381)	-0.79 (0.298)	-0.04 (0.223)	-0.56 (0.166)	
95% CI [2]	-1.39, 0.13	-1.38, -0.19	-0.48, 0.41	-0.89, -0.23	
Difference (95% CI) in CFB [2]		-0.16 (-0.95, 0.63)		-0.52 (-1.01, -0.03)	
Hedges'G (95% CI) in CFB		-0.08 (-0.60, 0.43)		-0.37 (-0.77, 0.03)	
p-value [3]		0.685		0.038	
					0.438

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	2.2 (1.30)	2.2 (1.30)	2.7 (1.18)	2.9 (1.21)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	2.0 (1.43)	1.7 (1.26)	2.6 (0.98)	2.2 (1.32)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	-0.33 (0.265)	-0.46 (0.207)	-0.12 (0.191)	-0.56 (0.145)	
95% CI [2]	-0.85, 0.20	-0.87, -0.05	-0.49, 0.26	-0.85, -0.27	
Difference (95% CI) in CFB [2]		-0.14 (-0.71, 0.44)		-0.44 (-0.86, -0.02)	
p-value [3]		0.641		0.039	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	51	37	76	
Mean (StdDev)	2.0 (1.20)	1.6 (1.33)	2.5 (1.19)	2.0 (1.28)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	-0.20 (0.272)	-0.44 (0.215)	-0.23 (0.203)	-0.88 (0.151)	
95% CI [2]	-0.74, 0.35	-0.87, -0.02	-0.63, 0.17	-1.18, -0.58	
Difference (95% CI) in CFB [2]		-0.25 (-0.84, 0.35)		-0.65 (-1.10, -0.20)	
p-value [3]		0.411		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	1.7 (1.43)	1.4 (1.21)	2.3 (1.20)	2.3 (1.34)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	-0.46 (0.307)	-0.86 (0.229)	-0.30 (0.227)	-0.55 (0.169)	
95% CI [2]	-1.08, 0.15	-1.31, -0.40	-0.74, 0.15	-0.88, -0.21	
Difference (95% CI) in CFB [2]		-0.39 (-1.03, 0.24)		-0.25 (-0.75, 0.25)	
p-value [3]		0.219		0.320	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	36	78	
Mean (StdDev)	1.9 (1.35)	1.5 (1.18)	2.4 (1.07)	1.8 (1.27)	
Median	2.0	1.0	2.5	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	42	36	77	
LS Mean (StdErr) [2]	-0.48 (0.245)	-0.79 (0.200)	-0.18 (0.238)	-0.92 (0.176)	
95% CI [2]	-0.97, 0.01	-1.19, -0.39	-0.65, 0.29	-1.27, -0.58	
Difference (95% CI) in CFB [2]		-0.31 (-0.84, 0.23)		-0.74 (-1.27, -0.22)	
p-value [3]		0.256		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	2.0 (1.50)	1.1 (1.01)	2.6 (1.07)	2.1 (1.31)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	-0.29 (0.263)	-1.09 (0.201)	-0.03 (0.228)	-0.63 (0.169)	
95% CI [2]	-0.82, 0.23	-1.49, -0.69	-0.48, 0.42	-0.97, -0.30	
Difference (95% CI) in CFB [2]		-0.80 (-1.37, -0.22)		-0.60 (-1.10, -0.10)	
p-value [3]		0.007		0.020	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	2.0 (1.40)	1.3 (1.23)	2.2 (1.21)	2.0 (1.34)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-0.32 (0.288)	-1.00 (0.225)	-0.35 (0.248)	-0.71 (0.183)	
95% CI [2]	-0.90, 0.25	-1.45, -0.55	-0.84, 0.14	-1.07, -0.34	
Difference (95% CI) in CFB [2]		-0.67 (-1.27, -0.08)		-0.36 (-0.91, 0.19)	
Hedges'G (95% CI) in CFB		-0.45 (-0.99, 0.05)		-0.23 (-0.63, 0.17)	
p-value [3]		0.028		0.194	
					0.422

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	2.0 (1.36)	2.3 (1.13)	2.6 (1.33)	2.4 (1.08)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	1.8 (1.08)	1.8 (1.19)	2.3 (1.25)	1.8 (1.24)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	-0.08 (0.255)	-0.50 (0.200)	-0.22 (0.199)	-0.48 (0.151)	
95% CI [2]	-0.59, 0.43	-0.89, -0.10	-0.61, 0.18	-0.77, -0.18	
Difference (95% CI) in CFB [2]		-0.42 (-0.98, 0.14)		-0.26 (-0.69, 0.18)	
p-value [3]		0.138		0.247	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	51	37	76	
Mean (StdDev)	1.6 (1.17)	1.7 (1.07)	2.2 (1.47)	1.7 (1.18)	
Median	1.5	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	-0.28 (0.231)	-0.51 (0.183)	-0.30 (0.197)	-0.63 (0.146)	
95% CI [2]	-0.74, 0.18	-0.88, -0.15	-0.69, 0.09	-0.91, -0.34	
Difference (95% CI) in CFB [2]		-0.24 (-0.74, 0.27)		-0.33 (-0.76, 0.11)	
p-value [3]		0.354		0.140	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	1.8 (1.31)	1.6 (1.06)	2.2 (1.37)	1.8 (1.32)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	-0.37 (0.325)	-0.85 (0.242)	-0.27 (0.220)	-0.56 (0.164)	
95% CI [2]	-1.01, 0.28	-1.34, -0.37	-0.71, 0.16	-0.89, -0.24	
Difference (95% CI) in CFB [2]		-0.49 (-1.16, 0.18)		-0.29 (-0.78, 0.19)	
p-value [3]		0.152		0.233	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	36	78	
Mean (StdDev)	1.6 (1.36)	1.6 (1.12)	2.4 (1.22)	1.6 (1.31)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	42	36	77	
LS Mean (StdErr) [2]	-0.25 (0.286)	-0.74 (0.234)	-0.11 (0.230)	-0.79 (0.170)	
95% CI [2]	-0.82, 0.32	-1.21, -0.27	-0.57, 0.34	-1.13, -0.45	
Difference (95% CI) in CFB [2]		-0.49 (-1.12, 0.13)		-0.67 (-1.18, -0.17)	
p-value [3]		0.120		0.010	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	1.9 (1.36)	1.4 (1.01)	2.4 (1.30)	1.6 (1.36)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	0.16 (0.309)	-0.85 (0.237)	-0.07 (0.220)	-0.71 (0.163)	
95% CI [2]	-0.46, 0.78	-1.32, -0.37	-0.51, 0.36	-1.04, -0.39	
Difference (95% CI) in CFB [2]		-1.01 (-1.68, -0.33)		-0.64 (-1.12, -0.15)	
p-value [3]		0.004		0.011	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	1.6 (1.33)	1.5 (1.20)	2.2 (1.29)	1.8 (1.32)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-0.05 (0.339)	-0.86 (0.265)	-0.22 (0.220)	-0.58 (0.163)	
95% CI [2]	-0.73, 0.62	-1.38, -0.33	-0.66, 0.21	-0.91, -0.26	
Difference (95% CI) in CFB [2]		-0.80 (-1.51, -0.10)		-0.36 (-0.85, 0.12)	
Hedges'G (95% CI) in CFB		-0.46 (-0.99, 0.04)		-0.26 (-0.66, 0.14)	
p-value [3]		0.026		0.141	
					0.299

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	1.4 (1.54)	1.4 (1.52)	1.9 (1.52)	2.1 (1.39)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	1.7 (1.59)	1.2 (1.34)	1.8 (1.46)	1.8 (1.47)	
Median	2.0	1.0	1.5	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	0.32 (0.243)	-0.17 (0.190)	-0.21 (0.179)	-0.34 (0.136)	
95% CI [2]	-0.17, 0.80	-0.54, 0.21	-0.56, 0.15	-0.61, -0.07	
Difference (95% CI) in CFB [2]		-0.48 (-1.01, 0.05)		-0.13 (-0.53, 0.26)	
p-value [3]		0.073		0.506	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	51	37	76	
Mean (StdDev)	1.5 (1.68)	1.1 (1.39)	1.5 (1.46)	1.6 (1.35)	
Median	1.0	0.0	1.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	0.15 (0.244)	-0.10 (0.192)	-0.36 (0.192)	-0.51 (0.142)	
95% CI [2]	-0.34, 0.63	-0.49, 0.28	-0.74, 0.02	-0.79, -0.23	
Difference (95% CI) in CFB [2]		-0.25 (-0.79, 0.28)		-0.15 (-0.57, 0.28)	
p-value [3]		0.353		0.498	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	1.7 (1.50)	0.9 (1.23)	1.5 (1.26)	1.6 (1.41)	
Median	1.0	0.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	0.18 (0.364)	-0.21 (0.271)	-0.36 (0.213)	-0.48 (0.159)	
95% CI [2]	-0.55, 0.91	-0.76, 0.33	-0.78, 0.06	-0.79, -0.16	
Difference (95% CI) in CFB [2]		-0.39 (-1.15, 0.36)		-0.12 (-0.59, 0.35)	
p-value [3]		0.298		0.618	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	36	77	
Mean (StdDev)	1.2 (1.47)	1.0 (1.23)	1.5 (1.34)	1.4 (1.36)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	42	36	76	
LS Mean (StdErr) [2]	0.00 (0.338)	-0.17 (0.276)	-0.30 (0.221)	-0.65 (0.164)	
95% CI [2]	-0.67, 0.68	-0.72, 0.38	-0.74, 0.14	-0.97, -0.32	
Difference (95% CI) in CFB [2]		-0.18 (-0.91, 0.56)		-0.35 (-0.84, 0.14)	
p-value [3]		0.636		0.160	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	1.3 (1.57)	0.9 (1.23)	1.5 (1.26)	1.6 (1.48)	
Median	1.0	0.0	1.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	-0.06 (0.347)	-0.39 (0.266)	-0.40 (0.244)	-0.53 (0.181)	
95% CI [2]	-0.75, 0.64	-0.92, 0.14	-0.89, 0.08	-0.89, -0.18	
Difference (95% CI) in CFB [2]		-0.34 (-1.09, 0.42)		-0.13 (-0.67, 0.41)	
p-value [3]		0.377		0.632	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	1.0 (1.22)	0.9 (1.40)	1.8 (1.46)	1.6 (1.35)	
Median	1.0	0.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-0.07 (0.321)	-0.20 (0.251)	-0.05 (0.242)	-0.44 (0.179)	
95% CI [2]	-0.71, 0.57	-0.70, 0.30	-0.53, 0.43	-0.80, -0.08	
Difference (95% CI) in CFB [2]		-0.13 (-0.80, 0.54)		-0.39 (-0.92, 0.15)	
Hedges'G (95% CI) in CFB		-0.08 (-0.59, 0.43)		-0.25 (-0.66, 0.14)	
p-value [3]		0.699		0.152	
					0.523

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	1.7 (1.34)	1.9 (1.22)	2.6 (1.13)	2.6 (1.06)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	1.3 (1.18)	1.4 (1.11)	2.2 (1.08)	2.1 (1.15)	
Median	1.0	1.0	3.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	-0.45 (0.218)	-0.54 (0.170)	-0.28 (0.146)	-0.44 (0.111)	
95% CI [2]	-0.89, -0.02	-0.88, -0.21	-0.57, 0.01	-0.66, -0.22	
Difference (95% CI) in CFB [2]		-0.09 (-0.57, 0.38)		-0.16 (-0.48, 0.16)	
p-value [3]		0.700		0.327	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	51	37	76	
Mean (StdDev)	1.6 (1.33)	1.2 (1.08)	2.1 (1.21)	1.8 (1.32)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	0.05 (0.213)	-0.57 (0.168)	-0.44 (0.182)	-0.81 (0.135)	
95% CI [2]	-0.37, 0.48	-0.90, -0.23	-0.80, -0.08	-1.08, -0.55	
Difference (95% CI) in CFB [2]		-0.62 (-1.09, -0.15)		-0.37 (-0.77, 0.03)	
p-value [3]		0.010		0.071	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	1.5 (1.24)	1.1 (1.04)	2.1 (1.10)	1.8 (1.19)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	-0.09 (0.275)	-0.80 (0.205)	-0.39 (0.166)	-0.69 (0.124)	
95% CI [2]	-0.64, 0.46	-1.21, -0.39	-0.72, -0.06	-0.93, -0.44	
Difference (95% CI) in CFB [2]		-0.71 (-1.28, -0.14)		-0.29 (-0.66, 0.07)	
p-value [3]		0.015		0.115	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	36	78	
Mean (StdDev)	1.3 (1.35)	1.1 (1.15)	2.1 (0.96)	1.7 (1.23)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	42	36	77	
LS Mean (StdErr) [2]	-0.50 (0.260)	-0.92 (0.213)	-0.37 (0.193)	-0.94 (0.143)	
95% CI [2]	-1.02, 0.02	-1.35, -0.50	-0.75, 0.01	-1.22, -0.66	
Difference (95% CI) in CFB [2]		-0.42 (-0.99, 0.15)		-0.57 (-1.00, -0.14)	
p-value [3]		0.146		0.009	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	1.8 (1.43)	0.9 (1.04)	2.2 (1.04)	1.9 (1.34)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	0.16 (0.267)	-1.09 (0.204)	-0.30 (0.193)	-0.65 (0.143)	
95% CI [2]	-0.37, 0.70	-1.50, -0.69	-0.68, 0.09	-0.93, -0.37	
Difference (95% CI) in CFB [2]		-1.26 (-1.84, -0.67)		-0.35 (-0.78, 0.07)	
p-value [3]		<0.0001		0.103	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	1.3 (1.40)	1.0 (1.16)	2.3 (1.19)	1.8 (1.30)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-0.29 (0.258)	-0.87 (0.202)	-0.15 (0.197)	-0.72 (0.146)	
95% CI [2]	-0.81, 0.22	-1.27, -0.47	-0.54, 0.24	-1.01, -0.43	
Difference (95% CI) in CFB [2]		-0.58 (-1.11, -0.04)		-0.57 (-1.01, -0.13)	
Hedges'G (95% CI) in CFB		-0.43 (-0.96, 0.07)		-0.45 (-0.86, -0.06)	
p-value [3]		0.036		0.011	
					0.996

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	1.5 (1.48)	1.8 (1.25)	2.3 (1.23)	2.3 (1.29)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	1.1 (1.19)	1.2 (1.15)	1.8 (1.13)	1.8 (1.29)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	-0.39 (0.224)	-0.64 (0.175)	-0.40 (0.173)	-0.31 (0.131)	
95% CI [2]	-0.84, 0.06	-0.99, -0.29	-0.74, -0.05	-0.57, -0.05	
Difference (95% CI) in CFB [2]		-0.25 (-0.74, 0.24)		0.09 (-0.29, 0.47)	
p-value [3]		0.318		0.645	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	51	37	76	
Mean (StdDev)	1.2 (1.22)	1.3 (1.23)	1.9 (1.26)	1.5 (1.30)	
Median	1.0	1.0	2.0	1.5	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	-0.32 (0.208)	-0.58 (0.164)	-0.27 (0.188)	-0.62 (0.140)	
95% CI [2]	-0.74, 0.09	-0.91, -0.26	-0.64, 0.10	-0.90, -0.34	
Difference (95% CI) in CFB [2]		-0.26 (-0.72, 0.19)		-0.35 (-0.77, 0.06)	
p-value [3]		0.257		0.097	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	1.2 (1.13)	1.0 (1.05)	1.8 (1.13)	1.5 (1.32)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	-0.60 (0.253)	-0.91 (0.189)	-0.32 (0.181)	-0.66 (0.135)	
95% CI [2]	-1.11, -0.10	-1.28, -0.53	-0.68, 0.04	-0.92, -0.39	
Difference (95% CI) in CFB [2]		-0.30 (-0.83, 0.22)		-0.34 (-0.73, 0.06)	
p-value [3]		0.251		0.100	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	36	78	
Mean (StdDev)	1.1 (1.32)	1.1 (1.09)	1.8 (1.24)	1.4 (1.27)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	42	36	77	
LS Mean (StdErr) [2]	-0.41 (0.241)	-0.91 (0.197)	-0.32 (0.208)	-0.76 (0.154)	
95% CI [2]	-0.89, 0.07	-1.31, -0.52	-0.73, 0.10	-1.06, -0.45	
Difference (95% CI) in CFB [2]		-0.50 (-1.03, 0.02)		-0.44 (-0.90, 0.02)	
p-value [3]		0.061		0.060	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	1.3 (1.35)	0.9 (1.11)	1.9 (1.17)	1.6 (1.36)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	-0.23 (0.250)	-1.10 (0.192)	-0.27 (0.198)	-0.63 (0.147)	
95% CI [2]	-0.73, 0.27	-1.48, -0.71	-0.67, 0.12	-0.92, -0.34	
Difference (95% CI) in CFB [2]		-0.87 (-1.41, -0.32)		-0.36 (-0.79, 0.08)	
p-value [3]		0.002		0.108	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	1.1 (1.27)	0.8 (1.17)	1.8 (1.31)	1.5 (1.34)	
Median	1.0	0.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-0.09 (0.263)	-0.94 (0.206)	-0.26 (0.199)	-0.57 (0.147)	
95% CI [2]	-0.61, 0.44	-1.35, -0.53	-0.66, 0.13	-0.86, -0.27	
Difference (95% CI) in CFB [2]		-0.85 (-1.40, -0.31)		-0.30 (-0.74, 0.14)	
Hedges'G (95% CI) in CFB		-0.63 (-1.17, -0.13)		-0.24 (-0.64, 0.16)	
p-value [3]		0.003		0.177	
					0.118

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	2.9 (0.83)	2.9 (0.98)	3.0 (1.03)	2.8 (1.07)	
Median	3.0	3.0	3.0	3.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	2.5 (0.93)	2.6 (0.95)	2.6 (1.18)	2.4 (1.07)	
Median	3.0	3.0	3.0	2.0	
Min, Max	1, 4	1, 4	0, 4	0, 4	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	-0.53 (0.185)	-0.41 (0.144)	-0.45 (0.169)	-0.44 (0.128)	
95% CI [2]	-0.90, -0.17	-0.70, -0.13	-0.79, -0.12	-0.69, -0.19	
Difference (95% CI) in CFB [2]		0.12 (-0.28, 0.52)		0.01 (-0.36, 0.39)	
p-value [3]		0.553		0.940	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	51	37	76	
Mean (StdDev)	2.5 (1.01)	2.5 (1.03)	2.6 (1.14)	2.0 (1.20)	
Median	2.5	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	-0.45 (0.186)	-0.46 (0.147)	-0.30 (0.188)	-0.63 (0.139)	
95% CI [2]	-0.82, -0.08	-0.76, -0.17	-0.67, 0.08	-0.91, -0.35	
Difference (95% CI) in CFB [2]		-0.02 (-0.42, 0.39)		-0.33 (-0.75, 0.08)	
p-value [3]		0.940		0.113	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	2.4 (1.27)	2.3 (0.94)	2.3 (1.25)	2.2 (1.39)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	-0.60 (0.254)	-0.56 (0.189)	-0.56 (0.196)	-0.44 (0.146)	
95% CI [2]	-1.11, -0.09	-0.94, -0.18	-0.95, -0.17	-0.73, -0.15	
Difference (95% CI) in CFB [2]		0.04 (-0.49, 0.56)		0.12 (-0.31, 0.55)	
p-value [3]		0.880		0.578	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	37	78	
Mean (StdDev)	2.5 (1.12)	2.2 (1.03)	2.5 (1.07)	1.9 (1.39)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	42	37	77	
LS Mean (StdErr) [2]	-0.54 (0.250)	-0.78 (0.204)	-0.52 (0.220)	-0.86 (0.164)	
95% CI [2]	-1.04, -0.04	-1.19, -0.38	-0.96, -0.09	-1.19, -0.54	
Difference (95% CI) in CFB [2]		-0.24 (-0.79, 0.30)		-0.34 (-0.83, 0.14)	
p-value [3]		0.376		0.167	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	2.3 (1.24)	2.1 (1.08)	2.6 (1.18)	2.1 (1.35)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	-0.48 (0.263)	-0.73 (0.201)	-0.22 (0.208)	-0.58 (0.154)	
95% CI [2]	-1.00, 0.05	-1.13, -0.32	-0.63, 0.19	-0.88, -0.27	
Difference (95% CI) in CFB [2]		-0.25 (-0.82, 0.32)		-0.36 (-0.82, 0.10)	
p-value [3]		0.387		0.125	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	2.3 (1.17)	2.2 (0.90)	2.6 (1.09)	2.1 (1.31)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-0.58 (0.239)	-0.82 (0.187)	-0.33 (0.214)	-0.56 (0.158)	
95% CI [2]	-1.06, -0.11	-1.19, -0.45	-0.76, 0.09	-0.87, -0.25	
Difference (95% CI) in CFB [2]		-0.24 (-0.73, 0.26)		-0.23 (-0.70, 0.25)	
Hedges'G (95% CI) in CFB		-0.19 (-0.71, 0.32)		-0.17 (-0.57, 0.23)	
p-value [3]		0.346		0.344	
					0.976

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	2.0 (1.51)	2.4 (1.18)	2.7 (1.39)	2.5 (1.23)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	2.0 (1.34)	2.0 (1.15)	2.3 (1.21)	1.9 (1.44)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	-0.08 (0.238)	-0.49 (0.186)	-0.45 (0.173)	-0.53 (0.131)	
95% CI [2]	-0.55, 0.40	-0.86, -0.12	-0.79, -0.11	-0.79, -0.27	
Difference (95% CI) in CFB [2]		-0.41 (-0.93, 0.11)		-0.07 (-0.45, 0.31)	
p-value [3]		0.120		0.699	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	51	37	76	
Mean (StdDev)	2.0 (1.38)	1.9 (1.16)	2.4 (1.14)	1.7 (1.33)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	-0.09 (0.277)	-0.66 (0.219)	-0.30 (0.187)	-0.69 (0.138)	
95% CI [2]	-0.64, 0.46	-1.09, -0.22	-0.67, 0.07	-0.97, -0.42	
Difference (95% CI) in CFB [2]		-0.57 (-1.17, 0.04)		-0.40 (-0.81, 0.02)	
p-value [3]		0.067		0.059	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	1.9 (1.49)	1.8 (1.27)	2.2 (1.28)	1.8 (1.45)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	-0.15 (0.237)	-0.64 (0.177)	-0.49 (0.201)	-0.63 (0.150)	
95% CI [2]	-0.63, 0.32	-0.99, -0.29	-0.89, -0.09	-0.92, -0.33	
Difference (95% CI) in CFB [2]		-0.49 (-0.98, 0.00)		-0.14 (-0.58, 0.31)	
p-value [3]		0.052		0.542	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	37	78	
Mean (StdDev)	1.7 (1.56)	1.8 (1.17)	2.1 (1.44)	1.7 (1.56)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	42	37	77	
LS Mean (StdErr) [2]	-0.28 (0.229)	-0.79 (0.188)	-0.54 (0.217)	-0.74 (0.161)	
95% CI [2]	-0.74, 0.18	-1.17, -0.42	-0.97, -0.11	-1.06, -0.42	
Difference (95% CI) in CFB [2]		-0.51 (-1.01, -0.01)		-0.21 (-0.69, 0.27)	
p-value [3]		0.047		0.392	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	2.0 (1.49)	1.6 (1.23)	2.4 (1.23)	1.7 (1.44)	
Median	2.0	1.5	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	0.06 (0.269)	-0.91 (0.206)	-0.33 (0.193)	-0.79 (0.143)	
95% CI [2]	-0.48, 0.60	-1.32, -0.50	-0.71, 0.05	-1.07, -0.51	
Difference (95% CI) in CFB [2]		-0.97 (-1.56, -0.38)		-0.46 (-0.88, -0.03)	
p-value [3]		0.002		0.035	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	1.8 (1.59)	1.3 (1.24)	2.2 (1.36)	1.6 (1.48)	
Median	2.0	1.0	3.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-0.32 (0.276)	-1.01 (0.216)	-0.42 (0.218)	-0.79 (0.161)	
95% CI [2]	-0.87, 0.24	-1.45, -0.58	-0.85, 0.01	-1.11, -0.47	
Difference (95% CI) in CFB [2]		-0.70 (-1.27, -0.13)		-0.37 (-0.85, 0.11)	
Hedges'G (95% CI) in CFB		-0.49 (-1.03, 0.01)		-0.27 (-0.67, 0.13)	
p-value [3]		0.018		0.129	
					0.406

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	2.5 (1.25)	2.6 (0.97)	3.1 (0.94)	3.1 (0.95)	
Median	3.0	3.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	1.9 (1.16)	1.8 (1.17)	2.6 (1.01)	2.5 (1.19)	
Median	2.0	2.0	2.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	-0.61 (0.218)	-0.77 (0.171)	-0.56 (0.167)	-0.67 (0.127)	
95% CI [2]	-1.05, -0.18	-1.11, -0.43	-0.89, -0.23	-0.92, -0.42	
Difference (95% CI) in CFB [2]		-0.15 (-0.63, 0.32)		-0.11 (-0.48, 0.26)	
p-value [3]		0.525		0.547	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	51	37	76	
Mean (StdDev)	2.0 (1.34)	1.8 (1.13)	2.7 (0.97)	2.1 (1.22)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	-0.48 (0.233)	-0.70 (0.184)	-0.33 (0.189)	-0.99 (0.140)	
95% CI [2]	-0.94, -0.01	-1.07, -0.33	-0.71, 0.04	-1.27, -0.71	
Difference (95% CI) in CFB [2]		-0.22 (-0.74, 0.29)		-0.66 (-1.07, -0.24)	
p-value [3]		0.385		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	2.1 (1.32)	1.7 (1.09)	2.6 (1.01)	2.2 (1.29)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	-0.45 (0.266)	-0.85 (0.198)	-0.38 (0.197)	-0.93 (0.147)	
95% CI [2]	-0.98, 0.08	-1.24, -0.45	-0.77, 0.01	-1.22, -0.63	
Difference (95% CI) in CFB [2]		-0.40 (-0.95, 0.15)		-0.54 (-0.98, -0.11)	
p-value [3]		0.155		0.015	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	37	77	
Mean (StdDev)	1.9 (1.25)	1.7 (1.15)	2.6 (1.04)	2.1 (1.20)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C5D1 CFB					
n	25	42	37	76	
LS Mean (StdErr) [2]	-0.67 (0.209)	-0.92 (0.171)	-0.37 (0.207)	-1.02 (0.154)	
95% CI [2]	-1.09, -0.26	-1.26, -0.57	-0.78, 0.04	-1.33, -0.72	
Difference (95% CI) in CFB [2]		-0.24 (-0.70, 0.21)		-0.65 (-1.11, -0.19)	
p-value [3]		0.291		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	2.2 (1.22)	1.4 (1.14)	2.6 (1.09)	2.1 (1.33)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	-0.33 (0.235)	-1.20 (0.180)	-0.39 (0.213)	-1.01 (0.158)	
95% CI [2]	-0.80, 0.14	-1.56, -0.84	-0.81, 0.04	-1.32, -0.69	
Difference (95% CI) in CFB [2]		-0.87 (-1.38, -0.35)		-0.62 (-1.09, -0.15)	
p-value [3]		0.001		0.010	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	1.8 (1.41)	1.4 (1.14)	2.6 (1.14)	2.2 (1.28)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-0.49 (0.268)	-1.08 (0.210)	-0.39 (0.206)	-0.85 (0.153)	
95% CI [2]	-1.03, 0.04	-1.49, -0.66	-0.80, 0.02	-1.15, -0.54	
Difference (95% CI) in CFB [2]		-0.58 (-1.14, -0.03)		-0.46 (-0.91, -0.00)	
Hedges'G (95% CI) in CFB		-0.42 (-0.95, 0.08)		-0.35 (-0.75, 0.05)	
p-value [3]		0.041		0.049	
					0.728

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	2.9 (1.04)	3.1 (0.98)	3.2 (0.81)	3.1 (0.96)	
Median	3.0	3.0	3.0	3.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	2.4 (1.06)	2.3 (0.99)	2.7 (0.93)	2.3 (1.16)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	-0.39 (0.193)	-0.80 (0.151)	-0.43 (0.172)	-0.65 (0.130)	
95% CI [2]	-0.77, -0.00	-1.10, -0.50	-0.77, -0.09	-0.91, -0.39	
Difference (95% CI) in CFB [2]		-0.41 (-0.83, 0.01)		-0.22 (-0.59, 0.16)	
p-value [3]		0.056		0.259	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	51	37	76	
Mean (StdDev)	2.4 (1.19)	2.2 (1.12)	2.6 (1.01)	2.0 (1.22)	
Median	3.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	-0.39 (0.229)	-0.81 (0.181)	-0.55 (0.201)	-0.99 (0.149)	
95% CI [2]	-0.85, 0.06	-1.17, -0.45	-0.95, -0.15	-1.29, -0.70	
Difference (95% CI) in CFB [2]		-0.41 (-0.92, 0.09)		-0.44 (-0.89, 0.00)	
p-value [3]		0.105		0.050	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	2.4 (1.34)	2.1 (1.06)	2.5 (1.04)	2.0 (1.21)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	-0.46 (0.272)	-1.04 (0.203)	-0.68 (0.187)	-1.02 (0.140)	
95% CI [2]	-1.01, 0.08	-1.45, -0.64	-1.05, -0.31	-1.30, -0.75	
Difference (95% CI) in CFB [2]		-0.58 (-1.14, -0.02)		-0.35 (-0.76, 0.07)	
p-value [3]		0.044		0.099	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	37	78	
Mean (StdDev)	2.2 (1.33)	2.1 (1.15)	2.5 (1.26)	2.0 (1.23)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	42	37	77	
LS Mean (StdErr) [2]	-0.47 (0.258)	-0.95 (0.211)	-0.67 (0.209)	-1.01 (0.156)	
95% CI [2]	-0.99, 0.04	-1.37, -0.53	-1.08, -0.25	-1.32, -0.71	
Difference (95% CI) in CFB [2]		-0.47 (-1.04, 0.09)		-0.35 (-0.81, 0.11)	
p-value [3]		0.097		0.137	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	2.4 (1.15)	1.8 (1.14)	2.7 (1.13)	2.1 (1.34)	
Median	3.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	-0.46 (0.264)	-1.29 (0.202)	-0.47 (0.208)	-0.97 (0.154)	
95% CI [2]	-0.99, 0.07	-1.69, -0.88	-0.89, -0.06	-1.27, -0.66	
Difference (95% CI) in CFB [2]		-0.83 (-1.41, -0.25)		-0.50 (-0.95, -0.04)	
p-value [3]		0.006		0.034	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	2.1 (1.42)	1.8 (1.23)	2.5 (1.26)	2.1 (1.24)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-0.49 (0.302)	-1.18 (0.236)	-0.62 (0.205)	-0.93 (0.152)	
95% CI [2]	-1.09, 0.12	-1.65, -0.70	-1.02, -0.21	-1.23, -0.63	
Difference (95% CI) in CFB [2]		-0.69 (-1.32, -0.06)		-0.32 (-0.77, 0.14)	
Hedges'G (95% CI) in CFB		-0.44 (-0.97, 0.06)		-0.24 (-0.64, 0.15)	
p-value [3]		0.032		0.170	
					0.345

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	2.5 (1.41)	1.9 (1.46)	1.9 (1.51)	1.8 (1.47)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	1.9 (1.45)	1.5 (1.41)	1.9 (1.42)	1.4 (1.38)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	-0.35 (0.246)	-0.26 (0.193)	0.23 (0.202)	-0.13 (0.153)	
95% CI [2]	-0.84, 0.14	-0.65, 0.12	-0.17, 0.63	-0.44, 0.17	
Difference (95% CI) in CFB [2]		0.09 (-0.45, 0.63)		-0.36 (-0.81, 0.08)	
p-value [3]		0.745		0.111	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	51	37	76	
Mean (StdDev)	2.1 (1.47)	1.5 (1.41)	1.8 (1.34)	1.2 (1.33)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	-0.28 (0.255)	-0.32 (0.201)	0.09 (0.237)	-0.41 (0.175)	
95% CI [2]	-0.79, 0.23	-0.73, 0.08	-0.38, 0.56	-0.75, -0.06	
Difference (95% CI) in CFB [2]		-0.04 (-0.60, 0.52)		-0.50 (-1.02, 0.03)	
p-value [3]		0.880		0.062	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	2.0 (1.31)	1.5 (1.36)	1.7 (1.27)	1.4 (1.41)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	-0.50 (0.250)	-0.29 (0.186)	-0.02 (0.228)	-0.27 (0.170)	
95% CI [2]	-1.00, -0.01	-0.66, 0.08	-0.48, 0.43	-0.61, 0.06	
Difference (95% CI) in CFB [2]		0.21 (-0.30, 0.73)		-0.25 (-0.75, 0.25)	
p-value [3]		0.410		0.328	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	37	78	
Mean (StdDev)	1.6 (1.34)	1.5 (1.38)	1.9 (1.36)	1.3 (1.37)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	42	37	77	
LS Mean (StdErr) [2]	-0.78 (0.298)	-0.30 (0.244)	0.22 (0.231)	-0.32 (0.172)	
95% CI [2]	-1.38, -0.18	-0.78, 0.19	-0.24, 0.68	-0.66, 0.02	
Difference (95% CI) in CFB [2]		0.49 (-0.17, 1.14)		-0.54 (-1.05, -0.03)	
p-value [3]		0.142		0.038	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	1.9 (1.54)	1.4 (1.29)	1.8 (1.41)	1.3 (1.35)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	-0.73 (0.287)	-0.45 (0.220)	0.09 (0.249)	-0.38 (0.185)	
95% CI [2]	-1.30, -0.15	-0.89, -0.01	-0.40, 0.59	-0.75, -0.01	
Difference (95% CI) in CFB [2]		0.28 (-0.35, 0.90)		-0.47 (-1.02, 0.08)	
p-value [3]		0.383		0.092	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	2.0 (1.54)	1.2 (1.23)	1.8 (1.47)	1.3 (1.36)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-0.26 (0.269)	-0.43 (0.210)	0.20 (0.262)	-0.27 (0.194)	
95% CI [2]	-0.80, 0.28	-0.85, -0.01	-0.32, 0.72	-0.66, 0.11	
Difference (95% CI) in CFB [2]		-0.17 (-0.73, 0.39)		-0.47 (-1.05, 0.11)	
Hedges'G (95% CI) in CFB		-0.12 (-0.64, 0.39)		-0.28 (-0.69, 0.11)	
p-value [3]		0.549		0.111	
					0.490

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	2.0 (1.43)	1.8 (1.23)	1.4 (1.03)	1.6 (1.36)	
Median	2.0	2.0	1.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	1.7 (1.18)	1.4 (1.26)	1.3 (1.00)	1.3 (1.21)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	-0.50 (0.194)	-0.54 (0.151)	-0.15 (0.143)	-0.39 (0.108)	
95% CI [2]	-0.88, -0.11	-0.84, -0.24	-0.43, 0.13	-0.61, -0.18	
Difference (95% CI) in CFB [2]		-0.04 (-0.47, 0.38)		-0.24 (-0.56, 0.07)	
p-value [3]		0.835		0.131	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	51	37	76	
Mean (StdDev)	1.7 (1.09)	1.3 (1.22)	1.3 (1.22)	0.9 (1.12)	
Median	2.0	1.0	1.0	0.5	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	-0.45 (0.244)	-0.68 (0.193)	-0.17 (0.194)	-0.75 (0.144)	
95% CI [2]	-0.93, 0.04	-1.06, -0.29	-0.55, 0.21	-1.04, -0.47	
Difference (95% CI) in CFB [2]		-0.23 (-0.77, 0.30)		-0.58 (-1.01, -0.16)	
p-value [3]		0.392		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	1.7 (1.22)	1.1 (1.15)	1.4 (1.17)	1.0 (1.18)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	-0.64 (0.282)	-0.70 (0.210)	-0.05 (0.196)	-0.75 (0.146)	
95% CI [2]	-1.20, -0.08	-1.12, -0.28	-0.44, 0.33	-1.04, -0.46	
Difference (95% CI) in CFB [2]		-0.06 (-0.64, 0.52)		-0.69 (-1.13, -0.26)	
p-value [3]		0.839		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	37	78	
Mean (StdDev)	1.6 (1.08)	1.1 (1.18)	1.4 (1.21)	0.9 (1.17)	
Median	2.0	1.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	42	37	77	
LS Mean (StdErr) [2]	-0.83 (0.217)	-0.92 (0.177)	-0.05 (0.200)	-0.75 (0.149)	
95% CI [2]	-1.27, -0.40	-1.28, -0.57	-0.45, 0.34	-1.05, -0.46	
Difference (95% CI) in CFB [2]		-0.09 (-0.56, 0.39)		-0.70 (-1.14, -0.26)	
p-value [3]		0.711		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	1.5 (1.08)	1.0 (1.15)	1.5 (1.24)	1.1 (1.20)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	-0.81 (0.250)	-0.90 (0.192)	0.03 (0.180)	-0.60 (0.134)	
95% CI [2]	-1.31, -0.31	-1.28, -0.51	-0.32, 0.39	-0.86, -0.33	
Difference (95% CI) in CFB [2]		-0.09 (-0.63, 0.46)		-0.63 (-1.03, -0.23)	
p-value [3]		0.750		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	1.2 (1.07)	1.0 (1.01)	1.4 (1.16)	1.0 (1.20)	
Median	1.0	1.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-1.18 (0.228)	-0.98 (0.179)	0.00 (0.194)	-0.59 (0.144)	
95% CI [2]	-1.64, -0.72	-1.34, -0.62	-0.38, 0.39	-0.88, -0.31	
Difference (95% CI) in CFB [2]		0.20 (-0.27, 0.68)		-0.60 (-1.03, -0.17)	
Hedges'G (95% CI) in CFB		0.17 (-0.34, 0.69)		-0.48 (-0.89, -0.09)	
p-value [3]		0.401		0.007	
					0.021

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	1.1 (1.33)	1.5 (1.55)	1.3 (1.25)	1.3 (1.39)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	1.3 (1.46)	1.3 (1.25)	1.1 (1.23)	1.1 (1.41)	
Median	1.0	1.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	0.23 (0.209)	-0.13 (0.163)	-0.16 (0.189)	-0.17 (0.143)	
95% CI [2]	-0.18, 0.65	-0.45, 0.20	-0.53, 0.22	-0.45, 0.11	
Difference (95% CI) in CFB [2]		-0.36 (-0.81, 0.10)		-0.01 (-0.43, 0.41)	
p-value [3]		0.122		0.961	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	51	37	76	
Mean (StdDev)	1.0 (1.07)	1.1 (1.27)	1.0 (1.29)	0.8 (1.13)	
Median	1.0	1.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	-0.06 (0.265)	-0.29 (0.210)	-0.15 (0.188)	-0.43 (0.140)	
95% CI [2]	-0.58, 0.47	-0.71, 0.13	-0.52, 0.22	-0.71, -0.16	
Difference (95% CI) in CFB [2]		-0.23 (-0.82, 0.35)		-0.28 (-0.70, 0.13)	
p-value [3]		0.425		0.178	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	1.3 (1.18)	1.0 (1.15)	1.3 (1.33)	0.9 (1.23)	
Median	1.0	1.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	-0.23 (0.306)	-0.64 (0.228)	0.05 (0.192)	-0.47 (0.143)	
95% CI [2]	-0.84, 0.39	-1.09, -0.18	-0.33, 0.43	-0.75, -0.18	
Difference (95% CI) in CFB [2]		-0.41 (-1.04, 0.22)		-0.52 (-0.94, -0.09)	
p-value [3]		0.199		0.017	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	37	78	
Mean (StdDev)	1.1 (1.28)	1.0 (1.25)	1.2 (1.24)	0.8 (1.15)	
Median	1.0	0.0	1.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	42	37	77	
LS Mean (StdErr) [2]	-0.14 (0.238)	-0.56 (0.194)	-0.01 (0.190)	-0.51 (0.141)	
95% CI [2]	-0.62, 0.33	-0.95, -0.17	-0.39, 0.37	-0.78, -0.23	
Difference (95% CI) in CFB [2]		-0.42 (-0.94, 0.10)		-0.49 (-0.91, -0.08)	
p-value [3]		0.110		0.021	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	1.2 (1.25)	0.9 (1.16)	1.2 (1.24)	0.8 (1.16)	
Median	1.0	0.5	1.0	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	-0.16 (0.273)	-0.67 (0.209)	-0.02 (0.184)	-0.47 (0.137)	
95% CI [2]	-0.71, 0.38	-1.09, -0.25	-0.38, 0.35	-0.74, -0.20	
Difference (95% CI) in CFB [2]		-0.50 (-1.10, 0.09)		-0.46 (-0.86, -0.05)	
p-value [3]		0.096		0.028	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	0.9 (1.08)	0.8 (1.09)	1.2 (1.25)	0.9 (1.29)	
Median	1.0	0.0	1.0	0.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-0.24 (0.272)	-0.61 (0.213)	0.08 (0.189)	-0.31 (0.140)	
95% CI [2]	-0.78, 0.31	-1.04, -0.19	-0.29, 0.46	-0.59, -0.04	
Difference (95% CI) in CFB [2]		-0.37 (-0.94, 0.19)		-0.40 (-0.81, 0.02)	
Hedges'G (95% CI) in CFB		-0.27 (-0.79, 0.24)		-0.33 (-0.74, 0.06)	
p-value [3]		0.192		0.062	
					0.976

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	1.9 (1.20)	2.0 (1.17)	2.0 (1.13)	1.8 (1.37)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	1.4 (1.31)	1.4 (1.26)	1.5 (1.22)	1.3 (1.26)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	-0.52 (0.232)	-0.93 (0.181)	-0.52 (0.179)	-0.41 (0.136)	
95% CI [2]	-0.98, -0.06	-1.29, -0.57	-0.88, -0.17	-0.68, -0.14	
Difference (95% CI) in CFB [2]		-0.41 (-0.92, 0.10)		0.11 (-0.28, 0.51)	
p-value [3]		0.111		0.572	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	51	37	76	
Mean (StdDev)	1.6 (1.16)	1.4 (1.09)	1.4 (1.09)	1.2 (1.16)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	-0.10 (0.252)	-0.62 (0.199)	-0.66 (0.156)	-0.63 (0.116)	
95% CI [2]	-0.60, 0.41	-1.02, -0.22	-0.96, -0.35	-0.86, -0.40	
Difference (95% CI) in CFB [2]		-0.52 (-1.08, 0.03)		0.03 (-0.32, 0.37)	
p-value [3]		0.063		0.882	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	1.3 (1.40)	1.2 (1.14)	1.6 (1.14)	1.4 (1.25)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	-0.27 (0.301)	-1.00 (0.224)	-0.48 (0.194)	-0.48 (0.145)	
95% CI [2]	-0.87, 0.33	-1.44, -0.55	-0.87, -0.10	-0.77, -0.19	
Difference (95% CI) in CFB [2]		-0.72 (-1.35, -0.10)		-0.00 (-0.43, 0.43)	
p-value [3]		0.023		>0.999	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	37	78	
Mean (StdDev)	1.1 (1.34)	1.0 (1.10)	1.6 (1.26)	1.1 (1.22)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	42	37	77	
LS Mean (StdErr) [2]	-0.50 (0.263)	-0.98 (0.215)	-0.33 (0.190)	-0.66 (0.141)	
95% CI [2]	-1.02, 0.03	-1.41, -0.55	-0.71, 0.04	-0.94, -0.38	
Difference (95% CI) in CFB [2]		-0.49 (-1.06, 0.09)		-0.33 (-0.74, 0.09)	
p-value [3]		0.096		0.126	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	1.5 (1.36)	0.9 (1.08)	1.5 (1.26)	1.1 (1.12)	
Median	1.0	0.5	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	-0.22 (0.272)	-1.49 (0.208)	-0.43 (0.192)	-0.76 (0.142)	
95% CI [2]	-0.76, 0.33	-1.90, -1.07	-0.81, -0.05	-1.04, -0.47	
Difference (95% CI) in CFB [2]		-1.27 (-1.86, -0.68)		-0.32 (-0.75, 0.10)	
p-value [3]		<0.0001		0.133	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	1.4 (1.45)	1.1 (1.09)	1.6 (1.32)	1.1 (1.29)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-0.15 (0.350)	-0.92 (0.274)	-0.33 (0.205)	-0.65 (0.152)	
95% CI [2]	-0.85, 0.55	-1.47, -0.37	-0.74, 0.08	-0.96, -0.35	
Difference (95% CI) in CFB [2]		-0.77 (-1.50, -0.04)		-0.33 (-0.78, 0.13)	
Hedges'G (95% CI) in CFB		-0.43 (-0.96, 0.08)		-0.25 (-0.65, 0.14)	
p-value [3]		0.038		0.157	
					0.274

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	2.3 (1.12)	2.5 (1.20)	2.3 (0.95)	2.1 (1.28)	
Median	2.0	3.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	1.9 (1.19)	1.6 (1.22)	1.6 (1.06)	1.6 (1.33)	
Median	2.0	1.0	1.5	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	-0.23 (0.211)	-0.86 (0.165)	-0.66 (0.180)	-0.39 (0.136)	
95% CI [2]	-0.65, 0.19	-1.18, -0.53	-1.02, -0.31	-0.66, -0.12	
Difference (95% CI) in CFB [2]		-0.63 (-1.09, -0.17)		0.28 (-0.12, 0.67)	
p-value [3]		0.008		0.169	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	51	37	76	
Mean (StdDev)	1.8 (1.22)	1.6 (1.18)	1.7 (1.07)	1.2 (1.07)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	-0.40 (0.261)	-0.75 (0.206)	-0.50 (0.184)	-0.78 (0.136)	
95% CI [2]	-0.92, 0.12	-1.16, -0.34	-0.86, -0.13	-1.05, -0.51	
Difference (95% CI) in CFB [2]		-0.35 (-0.92, 0.22)		-0.29 (-0.69, 0.12)	
p-value [3]		0.228		0.162	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	76	
Mean (StdDev)	1.8 (1.17)	1.5 (1.20)	1.7 (1.15)	1.4 (1.32)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	49	37	75	
LS Mean (StdErr) [2]	-0.54 (0.265)	-1.11 (0.197)	-0.62 (0.205)	-0.79 (0.154)	
95% CI [2]	-1.06, -0.01	-1.50, -0.71	-1.02, -0.21	-1.09, -0.48	
Difference (95% CI) in CFB [2]		-0.57 (-1.12, -0.02)		-0.17 (-0.62, 0.28)	
p-value [3]		0.041		0.459	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	37	78	
Mean (StdDev)	1.4 (1.45)	1.4 (1.15)	1.7 (1.23)	1.3 (1.25)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	42	37	77	
LS Mean (StdErr) [2]	-0.71 (0.288)	-1.04 (0.235)	-0.62 (0.209)	-0.86 (0.155)	
95% CI [2]	-1.29, -0.14	-1.51, -0.57	-1.04, -0.21	-1.16, -0.55	
Difference (95% CI) in CFB [2]		-0.33 (-0.95, 0.30)		-0.23 (-0.69, 0.23)	
p-value [3]		0.305		0.318	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	1.8 (1.40)	1.2 (1.22)	1.5 (1.15)	1.3 (1.28)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	-0.35 (0.253)	-1.49 (0.194)	-0.70 (0.215)	-0.71 (0.159)	
95% CI [2]	-0.85, 0.16	-1.88, -1.10	-1.13, -0.28	-1.02, -0.39	
Difference (95% CI) in CFB [2]		-1.14 (-1.69, -0.59)		-0.00 (-0.48, 0.47)	
p-value [3]		<0.001		0.987	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	1.5 (1.23)	1.3 (1.19)	1.5 (1.24)	1.3 (1.28)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-0.65 (0.300)	-1.10 (0.234)	-0.62 (0.213)	-0.64 (0.158)	
95% CI [2]	-1.25, -0.05	-1.57, -0.63	-1.04, -0.20	-0.95, -0.33	
Difference (95% CI) in CFB [2]		-0.44 (-1.07, 0.18)		-0.02 (-0.49, 0.45)	
Hedges'G (95% CI) in CFB		-0.29 (-0.81, 0.22)		-0.01 (-0.41, 0.38)	
p-value [3]		0.159		0.945	
					0.283

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	2.5 (1.25)	2.5 (1.10)	2.7 (1.01)	2.6 (1.15)	
Median	3.0	3.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	2.2 (1.06)	2.1 (1.18)	2.4 (1.17)	2.2 (1.17)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	-0.19 (0.185)	-0.47 (0.145)	-0.37 (0.175)	-0.48 (0.132)	
95% CI [2]	-0.56, 0.18	-0.76, -0.18	-0.72, -0.02	-0.74, -0.22	
Difference (95% CI) in CFB [2]		-0.28 (-0.68, 0.13)		-0.11 (-0.50, 0.27)	
p-value [3]		0.176		0.568	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	52	37	76	
Mean (StdDev)	2.2 (1.17)	2.2 (1.15)	2.3 (1.15)	2.0 (1.15)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	49	37	76	
LS Mean (StdErr) [2]	-0.20 (0.196)	-0.27 (0.155)	-0.49 (0.186)	-0.71 (0.138)	
95% CI [2]	-0.59, 0.19	-0.58, 0.04	-0.86, -0.12	-0.98, -0.44	
Difference (95% CI) in CFB [2]		-0.07 (-0.50, 0.36)		-0.22 (-0.63, 0.19)	
p-value [3]		0.750		0.284	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	2.2 (1.28)	2.0 (1.19)	2.4 (1.04)	2.0 (1.16)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	-0.24 (0.313)	-0.48 (0.233)	-0.29 (0.186)	-0.72 (0.139)	
95% CI [2]	-0.87, 0.38	-0.95, -0.02	-0.66, 0.08	-1.00, -0.45	
Difference (95% CI) in CFB [2]		-0.24 (-0.89, 0.40)		-0.43 (-0.84, -0.02)	
p-value [3]		0.455		0.042	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	37	78	
Mean (StdDev)	2.1 (1.24)	1.9 (1.11)	2.4 (1.01)	2.0 (1.18)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C5D1 CFB					
n	25	42	37	77	
LS Mean (StdErr) [2]	-0.41 (0.279)	-0.65 (0.228)	-0.37 (0.203)	-0.72 (0.151)	
95% CI [2]	-0.97, 0.14	-1.11, -0.20	-0.77, 0.04	-1.02, -0.42	
Difference (95% CI) in CFB [2]		-0.24 (-0.85, 0.37)		-0.35 (-0.80, 0.10)	
p-value [3]		0.437		0.122	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	2.2 (1.26)	1.6 (1.05)	2.4 (1.21)	1.9 (1.21)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	-0.22 (0.285)	-0.86 (0.218)	-0.33 (0.211)	-0.77 (0.157)	
95% CI [2]	-0.79, 0.35	-1.29, -0.42	-0.75, 0.09	-1.08, -0.46	
Difference (95% CI) in CFB [2]		-0.64 (-1.26, -0.01)		-0.45 (-0.91, 0.02)	
p-value [3]		0.045		0.060	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	2.0 (1.34)	1.7 (1.15)	2.4 (1.14)	1.9 (1.14)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-0.23 (0.275)	-0.75 (0.215)	-0.26 (0.209)	-0.72 (0.155)	
95% CI [2]	-0.78, 0.32	-1.18, -0.31	-0.68, 0.15	-1.03, -0.42	
Difference (95% CI) in CFB [2]		-0.52 (-1.09, 0.05)		-0.46 (-0.92, 0.00)	
Hedges'G (95% CI) in CFB		-0.36 (-0.89, 0.14)		-0.34 (-0.75, 0.05)	
p-value [3]		0.075		0.051	
					0.901

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	2.2 (1.44)	2.3 (1.29)	2.2 (1.33)	1.8 (1.30)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	1.8 (1.35)	1.8 (1.38)	1.9 (1.26)	1.5 (1.25)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	-0.31 (0.218)	-0.58 (0.171)	-0.20 (0.165)	-0.27 (0.125)	
95% CI [2]	-0.75, 0.12	-0.92, -0.25	-0.52, 0.13	-0.52, -0.02	
Difference (95% CI) in CFB [2]		-0.27 (-0.75, 0.20)		-0.07 (-0.44, 0.29)	
p-value [3]		0.255		0.691	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	29	52	37	76	
Mean (StdDev)	1.7 (1.32)	1.7 (1.24)	1.7 (1.24)	1.3 (1.21)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	26	49	37	76	
LS Mean (StdErr) [2]	-0.37 (0.211)	-0.47 (0.165)	-0.51 (0.187)	-0.57 (0.139)	
95% CI [2]	-0.79, 0.05	-0.80, -0.14	-0.88, -0.14	-0.84, -0.29	
Difference (95% CI) in CFB [2]		-0.10 (-0.56, 0.37)		-0.06 (-0.47, 0.35)	
p-value [3]		0.680		0.776	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	1.5 (1.44)	1.6 (1.27)	1.8 (1.30)	1.4 (1.31)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	-0.68 (0.289)	-0.81 (0.215)	-0.39 (0.200)	-0.51 (0.149)	
95% CI [2]	-1.26, -0.10	-1.24, -0.38	-0.79, 0.00	-0.81, -0.22	
Difference (95% CI) in CFB [2]		-0.13 (-0.72, 0.47)		-0.12 (-0.56, 0.32)	
p-value [3]		0.671		0.589	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	37	78	
Mean (StdDev)	1.4 (1.45)	1.4 (1.21)	1.9 (1.23)	1.2 (1.26)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	42	37	77	
LS Mean (StdErr) [2]	-0.82 (0.281)	-1.02 (0.229)	-0.28 (0.209)	-0.66 (0.155)	
95% CI [2]	-1.38, -0.26	-1.48, -0.56	-0.70, 0.13	-0.97, -0.36	
Difference (95% CI) in CFB [2]		-0.20 (-0.81, 0.41)		-0.38 (-0.84, 0.08)	
p-value [3]		0.519		0.105	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	1.9 (1.42)	1.3 (1.19)	1.8 (1.40)	1.3 (1.23)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	-0.19 (0.261)	-1.08 (0.200)	-0.31 (0.217)	-0.61 (0.161)	
95% CI [2]	-0.71, 0.33	-1.48, -0.68	-0.74, 0.12	-0.93, -0.29	
Difference (95% CI) in CFB [2]		-0.89 (-1.46, -0.32)		-0.30 (-0.78, 0.17)	
p-value [3]		0.003		0.211	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	1.7 (1.40)	1.4 (1.37)	1.8 (1.36)	1.1 (1.27)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-0.24 (0.254)	-0.66 (0.199)	-0.38 (0.207)	-0.72 (0.153)	
95% CI [2]	-0.74, 0.27	-1.06, -0.27	-0.80, 0.03	-1.03, -0.42	
Difference (95% CI) in CFB [2]		-0.43 (-0.96, 0.10)		-0.34 (-0.79, 0.12)	
Hedges'G (95% CI) in CFB		-0.33 (-0.85, 0.18)		-0.25 (-0.66, 0.14)	
p-value [3]		0.109		0.147	
					0.838

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	38	80	
Mean (StdDev)	2.4 (1.03)	2.5 (1.03)	2.4 (1.05)	2.3 (1.18)	
Median	2.0	3.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	2.0 (1.21)	1.8 (1.15)	1.8 (0.97)	1.8 (1.15)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	28	54	38	78	
LS Mean (StdErr) [2]	-0.17 (0.188)	-0.69 (0.147)	-0.66 (0.206)	-0.60 (0.156)	
95% CI [2]	-0.54, 0.21	-0.99, -0.40	-1.07, -0.25	-0.91, -0.29	
Difference (95% CI) in CFB [2]		-0.53 (-0.94, -0.12)		0.05 (-0.40, 0.51)	
p-value [3]		0.013		0.813	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	52	37	75	
Mean (StdDev)	1.9 (1.14)	1.8 (0.99)	2.0 (1.12)	1.6 (1.11)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	27	49	37	75	
LS Mean (StdErr) [2]	-0.46 (0.230)	-0.75 (0.182)	-0.40 (0.208)	-0.77 (0.154)	
95% CI [2]	-0.91, 0.00	-1.11, -0.38	-0.81, 0.01	-1.07, -0.46	
Difference (95% CI) in CFB [2]		-0.29 (-0.80, 0.21)		-0.36 (-0.82, 0.10)	
p-value [3]		0.256		0.120	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	1.7 (1.14)	1.7 (1.05)	2.0 (1.12)	1.6 (1.23)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	20	49	37	76	
LS Mean (StdErr) [2]	-0.69 (0.249)	-0.94 (0.186)	-0.42 (0.209)	-0.79 (0.156)	
95% CI [2]	-1.19, -0.19	-1.31, -0.57	-0.84, -0.01	-1.10, -0.48	
Difference (95% CI) in CFB [2]		-0.25 (-0.76, 0.27)		-0.37 (-0.83, 0.10)	
p-value [3]		0.339		0.119	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	37	78	
Mean (StdDev)	1.6 (1.37)	1.5 (1.12)	1.9 (1.03)	1.5 (1.18)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	25	42	37	77	
LS Mean (StdErr) [2]	-0.92 (0.296)	-1.19 (0.242)	-0.49 (0.207)	-0.89 (0.154)	
95% CI [2]	-1.51, -0.33	-1.67, -0.70	-0.90, -0.09	-1.19, -0.58	
Difference (95% CI) in CFB [2]		-0.27 (-0.92, 0.38)		-0.39 (-0.85, 0.06)	
p-value [3]		0.411		0.090	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	1.7 (1.31)	1.4 (1.07)	1.9 (1.08)	1.5 (1.20)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	23	47	37	76	
LS Mean (StdErr) [2]	-0.60 (0.261)	-1.19 (0.200)	-0.46 (0.215)	-0.89 (0.160)	
95% CI [2]	-1.13, -0.08	-1.59, -0.79	-0.88, -0.03	-1.21, -0.58	
Difference (95% CI) in CFB [2]		-0.59 (-1.16, -0.02)		-0.44 (-0.91, 0.04)	
p-value [3]		0.044		0.072	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	1.7 (1.22)	1.4 (1.21)	1.9 (1.33)	1.5 (1.29)	
Median	2.0	1.5	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	23	45	37	76	
LS Mean (StdErr) [2]	-0.45 (0.300)	-1.12 (0.235)	-0.47 (0.251)	-0.83 (0.186)	
95% CI [2]	-1.05, 0.15	-1.59, -0.65	-0.97, 0.03	-1.20, -0.46	
Difference (95% CI) in CFB [2]		-0.68 (-1.30, -0.05)		-0.36 (-0.92, 0.19)	
Hedges'G (95% CI) in CFB		-0.44 (-0.97, 0.07)		-0.23 (-0.63, 0.17)	
p-value [3]		0.034		0.197	
					0.500

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	29	55	38	80	
Mean (StdDev)	2.0 (1.41)	2.2 (1.19)	2.1 (1.15)	2.1 (1.18)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	1.8 (1.28)	1.7 (1.11)	1.9 (1.17)	1.8 (1.26)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	27	54	38	78	
LS Mean (StdErr) [2]	-0.21 (0.211)	-0.64 (0.164)	-0.08 (0.189)	-0.26 (0.143)	
95% CI [2]	-0.63, 0.21	-0.97, -0.31	-0.45, 0.29	-0.55, 0.02	
Difference (95% CI) in CFB [2]		-0.43 (-0.89, 0.03)		-0.18 (-0.60, 0.23)	
p-value [3]		0.066		0.388	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	52	37	76	
Mean (StdDev)	1.6 (1.22)	1.7 (1.13)	1.9 (1.15)	1.5 (1.11)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	26	49	37	76	
LS Mean (StdErr) [2]	-0.33 (0.207)	-0.60 (0.162)	-0.05 (0.186)	-0.57 (0.138)	
95% CI [2]	-0.75, 0.08	-0.93, -0.28	-0.42, 0.32	-0.84, -0.30	
Difference (95% CI) in CFB [2]		-0.27 (-0.72, 0.19)		-0.52 (-0.93, -0.11)	
p-value [3]		0.245		0.014	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	1.2 (1.13)	1.6 (1.16)	2.1 (1.20)	1.5 (1.30)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	19	49	37	76	
LS Mean (StdErr) [2]	-0.69 (0.300)	-0.66 (0.221)	-0.01 (0.196)	-0.68 (0.146)	
95% CI [2]	-1.29, -0.09	-1.10, -0.22	-0.40, 0.38	-0.97, -0.39	
Difference (95% CI) in CFB [2]		0.03 (-0.59, 0.65)		-0.67 (-1.10, -0.24)	
p-value [3]		0.922		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	37	78	
Mean (StdDev)	1.3 (1.07)	1.3 (1.07)	1.9 (1.08)	1.5 (1.17)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	24	42	37	77	
LS Mean (StdErr) [2]	-0.57 (0.270)	-0.89 (0.219)	-0.11 (0.198)	-0.60 (0.147)	
95% CI [2]	-1.11, -0.03	-1.33, -0.45	-0.50, 0.29	-0.89, -0.31	
Difference (95% CI) in CFB [2]		-0.32 (-0.91, 0.27)		-0.49 (-0.93, -0.05)	
p-value [3]		0.283		0.028	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	1.4 (1.19)	1.2 (1.10)	1.9 (1.19)	1.5 (1.25)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	22	47	37	76	
LS Mean (StdErr) [2]	-0.42 (0.289)	-1.09 (0.219)	-0.13 (0.198)	-0.70 (0.146)	
95% CI [2]	-1.00, 0.16	-1.53, -0.65	-0.52, 0.26	-0.99, -0.41	
Difference (95% CI) in CFB [2]		-0.67 (-1.30, -0.04)		-0.57 (-1.01, -0.13)	
p-value [3]		0.038		0.011	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.3a
Change from Baseline in MC-QoL Individual Item Scores by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	1.4 (1.04)	1.5 (1.16)	1.9 (1.23)	1.5 (1.31)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	22	45	37	76	
LS Mean (StdErr) [2]	-0.27 (0.287)	-0.69 (0.222)	-0.06 (0.222)	-0.54 (0.165)	
95% CI [2]	-0.84, 0.31	-1.13, -0.24	-0.50, 0.38	-0.87, -0.21	
Difference (95% CI) in CFB [2]		-0.42 (-1.02, 0.18)		-0.48 (-0.97, 0.01)	
Hedges'G (95% CI) in CFB		-0.29 (-0.82, 0.22)		-0.34 (-0.74, 0.06)	
p-value [3]		0.165		0.056	
					0.878

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-reg-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.4a
Change from Baseline in MC-QoL Individual Item Scores by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-cou-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	2.0 (1.23)	1.8 (1.02)	3.1 (0.89)	2.6 (1.10)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	1.9 (1.01)	1.3 (0.96)	2.5 (1.02)	1.8 (0.90)	
Median	2.0	1.0	2.5	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	-0.15 (0.198)	-0.49 (0.135)	-0.59 (0.187)	-0.76 (0.151)	
95% CI [2]	-0.55, 0.25	-0.76, -0.22	-0.96, -0.22	-1.06, -0.46	
Difference (95% CI) in CFB [2]		-0.34 (-0.76, 0.07)		-0.17 (-0.60, 0.26)	
p-value [3]		0.105		0.428	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	78	
Mean (StdDev)	1.4 (1.05)	1.2 (0.89)	2.4 (1.05)	1.7 (0.97)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	-0.50 (0.257)	-0.55 (0.169)	-0.70 (0.195)	-0.85 (0.161)	
95% CI [2]	-1.01, 0.02	-0.89, -0.21	-1.09, -0.31	-1.17, -0.53	
Difference (95% CI) in CFB [2]		-0.05 (-0.60, 0.49)		-0.15 (-0.61, 0.31)	
p-value [3]		0.842		0.517	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	1.8 (1.18)	1.0 (0.75)	2.4 (0.99)	1.6 (1.09)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 3	1, 4	0, 4	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	-0.35 (0.291)	-0.92 (0.198)	-0.60 (0.213)	-0.94 (0.164)	
95% CI [2]	-0.93, 0.23	-1.32, -0.53	-1.02, -0.18	-1.26, -0.61	
Difference (95% CI) in CFB [2]		-0.57 (-1.18, 0.04)		-0.34 (-0.82, 0.14)	
p-value [3]		0.065		0.168	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	44	41	78	
Mean (StdDev)	1.9 (1.24)	1.1 (0.98)	2.4 (1.14)	1.5 (0.99)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	21	41	41	76	
LS Mean (StdErr) [2]	-0.15 (0.296)	-0.83 (0.210)	-0.68 (0.206)	-1.05 (0.163)	
95% CI [2]	-0.74, 0.45	-1.25, -0.41	-1.09, -0.27	-1.37, -0.72	
Difference (95% CI) in CFB [2]		-0.68 (-1.30, -0.06)		-0.37 (-0.84, 0.11)	
p-value [3]		0.033		0.129	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	1.7 (1.22)	1.3 (0.93)	2.4 (1.16)	1.6 (1.12)	
Median	1.0	1.0	3.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	-0.26 (0.253)	-0.54 (0.173)	-0.79 (0.219)	-1.03 (0.170)	
95% CI [2]	-0.77, 0.24	-0.88, -0.19	-1.22, -0.35	-1.37, -0.69	
Difference (95% CI) in CFB [2]		-0.28 (-0.81, 0.26)		-0.24 (-0.75, 0.26)	
p-value [3]		0.304		0.343	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	1.9 (1.25)	1.3 (0.98)	2.5 (1.08)	1.4 (1.02)	
Median	2.0	1.0	2.5	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	-0.21 (0.226)	-0.63 (0.156)	-0.65 (0.207)	-1.10 (0.164)	
95% CI [2]	-0.66, 0.24	-0.94, -0.32	-1.06, -0.24	-1.43, -0.78	
Difference (95% CI) in CFB [2]		-0.41 (-0.88, 0.06)		-0.45 (-0.93, 0.02)	
Hedges'G (95% CI) in CFB		-0.39 (-0.95, 0.13)		-0.33 (-0.72, 0.06)	
p-value [3]		0.083		0.059	
					0.984

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	2.1 (1.08)	1.6 (1.02)	2.6 (1.18)	2.4 (1.12)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	1.8 (1.26)	1.3 (0.86)	2.3 (1.07)	1.5 (1.04)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	-0.21 (0.208)	-0.25 (0.142)	-0.31 (0.201)	-0.82 (0.162)	
95% CI [2]	-0.62, 0.20	-0.53, 0.04	-0.71, 0.09	-1.15, -0.50	
Difference (95% CI) in CFB [2]		-0.04 (-0.47, 0.40)		-0.51 (-0.98, -0.05)	
p-value [3]		0.873		0.031	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	78	
Mean (StdDev)	1.7 (1.12)	1.1 (0.87)	2.2 (1.26)	1.6 (1.05)	
Median	2.0	1.0	2.0	1.5	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	-0.41 (0.267)	-0.37 (0.175)	-0.40 (0.205)	-0.83 (0.169)	
95% CI [2]	-0.94, 0.13	-0.72, -0.02	-0.81, 0.00	-1.16, -0.49	
Difference (95% CI) in CFB [2]		0.04 (-0.52, 0.60)		-0.42 (-0.90, 0.05)	
p-value [3]		0.884		0.082	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	1.9 (1.31)	1.0 (0.70)	2.2 (0.99)	1.4 (1.15)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 2	0, 4	0, 4	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	-0.07 (0.258)	-0.46 (0.176)	-0.33 (0.213)	-0.91 (0.163)	
95% CI [2]	-0.58, 0.45	-0.81, -0.10	-0.76, 0.09	-1.23, -0.58	
Difference (95% CI) in CFB [2]		-0.39 (-0.93, 0.15)		-0.57 (-1.06, -0.09)	
p-value [3]		0.156		0.020	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	44	41	78	
Mean (StdDev)	1.7 (1.29)	1.2 (0.91)	2.2 (1.28)	1.4 (1.03)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	21	41	41	76	
LS Mean (StdErr) [2]	-0.26 (0.305)	-0.36 (0.216)	-0.37 (0.203)	-0.85 (0.161)	
95% CI [2]	-0.87, 0.35	-0.79, 0.08	-0.77, 0.03	-1.16, -0.53	
Difference (95% CI) in CFB [2]		-0.10 (-0.74, 0.55)		-0.47 (-0.94, -0.00)	
p-value [3]		0.764		0.048	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	1.8 (1.15)	1.1 (0.92)	2.2 (1.20)	1.6 (1.13)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	-0.14 (0.264)	-0.34 (0.180)	-0.27 (0.216)	-0.84 (0.167)	
95% CI [2]	-0.67, 0.39	-0.70, 0.02	-0.70, 0.15	-1.17, -0.51	
Difference (95% CI) in CFB [2]		-0.20 (-0.76, 0.35)		-0.56 (-1.06, -0.07)	
p-value [3]		0.467		0.027	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	1.9 (1.27)	1.3 (1.07)	2.2 (1.21)	1.4 (1.13)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	-0.11 (0.277)	-0.33 (0.191)	-0.31 (0.221)	-0.80 (0.175)	
95% CI [2]	-0.66, 0.45	-0.71, 0.05	-0.75, 0.12	-1.14, -0.45	
Difference (95% CI) in CFB [2]		-0.22 (-0.80, 0.35)		-0.49 (-0.99, 0.02)	
Hedges'G (95% CI) in CFB		-0.18 (-0.72, 0.36)		-0.33 (-0.72, 0.06)	
p-value [3]		0.438		0.059	
					0.566

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	1.6 (1.01)	1.8 (1.07)	2.6 (1.04)	2.6 (0.99)	
Median	1.5	2.0	3.0	3.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	1.6 (0.92)	1.5 (1.07)	2.3 (1.07)	2.0 (1.02)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	-0.18 (0.218)	-0.29 (0.149)	-0.27 (0.169)	-0.48 (0.136)	
95% CI [2]	-0.61, 0.26	-0.59, 0.01	-0.61, 0.06	-0.75, -0.21	
Difference (95% CI) in CFB [2]		-0.11 (-0.57, 0.35)		-0.21 (-0.60, 0.18)	
p-value [3]		0.631		0.298	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	78	
Mean (StdDev)	1.5 (0.86)	1.6 (1.13)	2.2 (1.01)	1.8 (1.09)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	-0.04 (0.278)	-0.23 (0.182)	-0.40 (0.183)	-0.70 (0.151)	
95% CI [2]	-0.59, 0.52	-0.59, 0.14	-0.76, -0.04	-1.00, -0.40	
Difference (95% CI) in CFB [2]		-0.19 (-0.78, 0.39)		-0.30 (-0.73, 0.13)	
p-value [3]		0.516		0.168	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	1.4 (0.80)	1.4 (1.00)	2.4 (1.10)	1.9 (1.00)	
Median	1.0	1.0	3.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	-0.32 (0.285)	-0.40 (0.194)	-0.18 (0.199)	-0.71 (0.153)	
95% CI [2]	-0.89, 0.25	-0.79, -0.01	-0.58, 0.21	-1.02, -0.41	
Difference (95% CI) in CFB [2]		-0.09 (-0.68, 0.51)		-0.53 (-0.98, -0.08)	
p-value [3]		0.771		0.022	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	44	41	78	
Mean (StdDev)	1.4 (1.16)	1.4 (0.89)	2.3 (1.17)	1.9 (1.08)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	21	41	41	76	
LS Mean (StdErr) [2]	-0.31 (0.325)	-0.34 (0.230)	-0.31 (0.191)	-0.69 (0.151)	
95% CI [2]	-0.96, 0.34	-0.80, 0.12	-0.69, 0.07	-0.99, -0.39	
Difference (95% CI) in CFB [2]		-0.02 (-0.71, 0.66)		-0.38 (-0.82, 0.06)	
p-value [3]		0.944		0.091	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	1.7 (1.06)	1.1 (0.91)	2.0 (1.21)	1.9 (1.10)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	0.02 (0.273)	-0.59 (0.187)	-0.48 (0.203)	-0.61 (0.158)	
95% CI [2]	-0.53, 0.56	-0.96, -0.21	-0.88, -0.08	-0.92, -0.30	
Difference (95% CI) in CFB [2]		-0.60 (-1.18, -0.03)		-0.13 (-0.60, 0.34)	
p-value [3]		0.039		0.574	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	1.5 (1.10)	1.3 (1.00)	2.1 (1.09)	1.8 (1.11)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	-0.15 (0.339)	-0.40 (0.234)	-0.41 (0.206)	-0.74 (0.163)	
95% CI [2]	-0.83, 0.52	-0.87, 0.06	-0.82, -0.00	-1.06, -0.42	
Difference (95% CI) in CFB [2]		-0.25 (-0.95, 0.46)		-0.33 (-0.80, 0.14)	
Hedges'G (95% CI) in CFB		-0.16 (-0.70, 0.37)		-0.24 (-0.63, 0.14)	
p-value [3]		0.483		0.163	
					0.858

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	1.6 (1.10)	2.0 (1.10)	2.3 (1.20)	2.2 (1.30)	
Median	2.0	2.0	2.5	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	49	44	85	
Mean (StdDev)	1.4 (1.19)	1.2 (1.01)	1.8 (1.17)	1.6 (1.15)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	23	47	43	83	
LS Mean (StdErr) [2]	0.10 (0.220)	-0.63 (0.154)	-0.51 (0.200)	-0.55 (0.161)	
95% CI [2]	-0.34, 0.54	-0.93, -0.32	-0.90, -0.11	-0.87, -0.24	
Difference (95% CI) in CFB [2]		-0.72 (-1.18, -0.26)		-0.05 (-0.51, 0.41)	
p-value [3]		0.002		0.842	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	78	
Mean (StdDev)	1.4 (1.14)	1.4 (1.19)	1.9 (1.35)	1.5 (1.10)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	0.09 (0.246)	-0.50 (0.161)	-0.42 (0.219)	-0.69 (0.181)	
95% CI [2]	-0.40, 0.58	-0.82, -0.18	-0.85, 0.02	-1.05, -0.34	
Difference (95% CI) in CFB [2]		-0.59 (-1.11, -0.08)		-0.28 (-0.79, 0.23)	
p-value [3]		0.025		0.285	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	1.4 (1.12)	1.2 (1.02)	1.9 (1.24)	1.6 (1.25)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	-0.01 (0.238)	-0.74 (0.162)	-0.55 (0.221)	-0.60 (0.169)	
95% CI [2]	-0.48, 0.47	-1.06, -0.41	-0.99, -0.11	-0.93, -0.26	
Difference (95% CI) in CFB [2]		-0.73 (-1.23, -0.23)		-0.05 (-0.55, 0.45)	
p-value [3]		0.005		0.853	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	44	41	78	
Mean (StdDev)	1.5 (1.08)	1.1 (1.06)	2.0 (1.09)	1.5 (1.19)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	21	41	41	76	
LS Mean (StdErr) [2]	0.19 (0.281)	-0.70 (0.199)	-0.37 (0.214)	-0.74 (0.169)	
95% CI [2]	-0.37, 0.75	-1.10, -0.31	-0.79, 0.05	-1.07, -0.40	
Difference (95% CI) in CFB [2]		-0.90 (-1.49, -0.30)		-0.37 (-0.86, 0.13)	
p-value [3]		0.004		0.143	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	1.5 (1.08)	1.2 (1.08)	1.9 (1.24)	1.4 (1.15)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	0.12 (0.272)	-0.64 (0.186)	-0.43 (0.215)	-0.72 (0.167)	
95% CI [2]	-0.42, 0.67	-1.01, -0.26	-0.85, -0.00	-1.06, -0.39	
Difference (95% CI) in CFB [2]		-0.76 (-1.33, -0.19)		-0.30 (-0.79, 0.20)	
p-value [3]		0.010		0.239	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	1.6 (1.01)	1.4 (1.08)	1.8 (1.15)	1.4 (1.29)	
Median	1.5	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	0.28 (0.229)	-0.52 (0.158)	-0.43 (0.227)	-0.63 (0.180)	
95% CI [2]	-0.18, 0.74	-0.83, -0.20	-0.88, 0.02	-0.99, -0.27	
Difference (95% CI) in CFB [2]		-0.80 (-1.27, -0.32)		-0.20 (-0.72, 0.32)	
Hedges'G (95% CI) in CFB		-0.75 (-1.33, -0.23)		-0.13 (-0.52, 0.26)	
p-value [3]		0.001		0.451	
					0.118

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	2.8 (0.93)	2.8 (1.03)	3.3 (0.83)	3.4 (0.79)	
Median	3.0	3.0	4.0	4.0	
Min, Max	1, 4	1, 4	1, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	2.6 (0.87)	2.2 (1.05)	2.9 (0.97)	2.9 (1.02)	
Median	3.0	2.0	3.0	3.0	
Min, Max	1, 4	0, 4	1, 4	0, 4	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	-0.08 (0.216)	-0.45 (0.147)	-0.45 (0.158)	-0.54 (0.127)	
95% CI [2]	-0.51, 0.35	-0.75, -0.16	-0.77, -0.14	-0.79, -0.29	
Difference (95% CI) in CFB [2]		-0.37 (-0.82, 0.08)		-0.09 (-0.45, 0.28)	
p-value [3]		0.106		0.639	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	78	
Mean (StdDev)	2.5 (0.91)	2.0 (0.98)	2.8 (1.15)	2.7 (1.08)	
Median	2.0	2.0	3.0	3.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	-0.21 (0.247)	-0.73 (0.162)	-0.57 (0.181)	-0.67 (0.150)	
95% CI [2]	-0.71, 0.28	-1.05, -0.40	-0.93, -0.21	-0.97, -0.37	
Difference (95% CI) in CFB [2]		-0.52 (-1.04, 0.00)		-0.10 (-0.53, 0.32)	
p-value [3]		0.052		0.625	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	2.4 (1.12)	2.2 (1.14)	2.9 (1.07)	2.6 (1.10)	
Median	2.0	2.0	3.0	3.0	
Min, Max	1, 4	0, 4	1, 4	0, 4	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	-0.24 (0.270)	-0.51 (0.184)	-0.58 (0.202)	-0.80 (0.155)	
95% CI [2]	-0.78, 0.30	-0.88, -0.14	-0.98, -0.18	-1.10, -0.49	
Difference (95% CI) in CFB [2]		-0.27 (-0.84, 0.29)		-0.22 (-0.68, 0.23)	
p-value [3]		0.340		0.339	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	44	41	78	
Mean (StdDev)	2.4 (1.12)	2.0 (1.03)	2.9 (1.22)	2.5 (1.15)	
Median	3.0	2.0	3.0	3.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	21	41	41	76	
LS Mean (StdErr) [2]	-0.31 (0.264)	-0.71 (0.187)	-0.57 (0.200)	-0.83 (0.158)	
95% CI [2]	-0.84, 0.22	-1.08, -0.33	-0.96, -0.17	-1.15, -0.52	
Difference (95% CI) in CFB [2]		-0.40 (-0.96, 0.16)		-0.27 (-0.73, 0.20)	
p-value [3]		0.160		0.255	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	2.4 (0.99)	2.0 (1.05)	2.7 (1.15)	2.5 (1.20)	
Median	2.0	2.0	3.0	3.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	-0.43 (0.255)	-0.78 (0.175)	-0.77 (0.209)	-0.93 (0.162)	
95% CI [2]	-0.94, 0.08	-1.12, -0.43	-1.18, -0.36	-1.25, -0.61	
Difference (95% CI) in CFB [2]		-0.35 (-0.88, 0.19)		-0.16 (-0.64, 0.32)	
p-value [3]		0.199		0.517	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	2.3 (0.98)	2.1 (0.91)	2.7 (1.11)	2.5 (1.14)	
Median	2.0	2.0	3.0	3.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	-0.42 (0.258)	-0.58 (0.178)	-0.67 (0.204)	-0.87 (0.161)	
95% CI [2]	-0.94, 0.10	-0.94, -0.23	-1.07, -0.27	-1.19, -0.56	
Difference (95% CI) in CFB [2]		-0.16 (-0.70, 0.37)		-0.21 (-0.67, 0.26)	
Hedges'G (95% CI) in CFB		-0.14 (-0.68, 0.40)		-0.15 (-0.54, 0.24)	
p-value [3]		0.542		0.383	
					0.880

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	1.5 (1.10)	1.8 (1.29)	2.4 (1.00)	2.3 (1.00)	
Median	1.5	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	1.5 (1.12)	1.5 (1.05)	2.2 (0.97)	1.9 (0.99)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	-0.07 (0.226)	-0.28 (0.154)	-0.21 (0.154)	-0.31 (0.125)	
95% CI [2]	-0.52, 0.38	-0.59, 0.03	-0.52, 0.09	-0.56, -0.07	
Difference (95% CI) in CFB [2]		-0.21 (-0.68, 0.26)		-0.10 (-0.46, 0.26)	
p-value [3]		0.379		0.584	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	78	
Mean (StdDev)	1.3 (0.99)	1.3 (0.93)	2.1 (1.05)	1.7 (1.02)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	-0.19 (0.287)	-0.54 (0.188)	-0.30 (0.170)	-0.49 (0.141)	
95% CI [2]	-0.77, 0.38	-0.91, -0.16	-0.64, 0.03	-0.77, -0.21	
Difference (95% CI) in CFB [2]		-0.35 (-0.95, 0.26)		-0.19 (-0.58, 0.21)	
p-value [3]		0.256		0.358	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	1.3 (1.15)	1.3 (0.99)	2.2 (1.12)	1.9 (1.19)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	-0.18 (0.308)	-0.49 (0.210)	-0.29 (0.186)	-0.32 (0.143)	
95% CI [2]	-0.79, 0.44	-0.91, -0.07	-0.66, 0.08	-0.60, -0.04	
Difference (95% CI) in CFB [2]		-0.32 (-0.96, 0.33)		-0.03 (-0.45, 0.39)	
p-value [3]		0.332		0.888	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	44	41	78	
Mean (StdDev)	1.3 (1.19)	1.3 (1.06)	2.2 (1.17)	1.9 (1.14)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	21	41	41	76	
LS Mean (StdErr) [2]	-0.30 (0.283)	-0.35 (0.201)	-0.27 (0.174)	-0.39 (0.137)	
95% CI [2]	-0.87, 0.26	-0.75, 0.05	-0.61, 0.08	-0.67, -0.12	
Difference (95% CI) in CFB [2]		-0.05 (-0.65, 0.55)		-0.13 (-0.53, 0.27)	
p-value [3]		0.866		0.533	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	1.3 (1.07)	1.2 (0.88)	2.1 (1.00)	1.8 (1.23)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	-0.31 (0.262)	-0.54 (0.179)	-0.32 (0.177)	-0.41 (0.137)	
95% CI [2]	-0.83, 0.22	-0.89, -0.18	-0.67, 0.03	-0.68, -0.14	
Difference (95% CI) in CFB [2]		-0.23 (-0.78, 0.32)		-0.09 (-0.50, 0.32)	
p-value [3]		0.408		0.659	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	1.2 (0.96)	1.4 (1.02)	2.1 (1.05)	1.7 (1.16)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	-0.42 (0.300)	-0.29 (0.207)	-0.33 (0.180)	-0.52 (0.142)	
95% CI [2]	-1.02, 0.18	-0.70, 0.13	-0.69, 0.02	-0.80, -0.23	
Difference (95% CI) in CFB [2]		0.13 (-0.49, 0.76)		-0.18 (-0.59, 0.23)	
Hedges'G (95% CI) in CFB		0.09 (-0.44, 0.63)		-0.15 (-0.54, 0.24)	
p-value [3]		0.676		0.384	
					0.397

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	2.0 (1.18)	2.1 (1.33)	3.1 (0.94)	3.1 (0.98)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	49	44	85	
Mean (StdDev)	2.0 (1.00)	1.8 (1.19)	2.5 (1.09)	2.4 (1.05)	
Median	2.0	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	23	47	43	83	
LS Mean (StdErr) [2]	0.14 (0.208)	-0.14 (0.145)	-0.63 (0.159)	-0.69 (0.128)	
95% CI [2]	-0.27, 0.56	-0.42, 0.15	-0.94, -0.31	-0.94, -0.44	
Difference (95% CI) in CFB [2]		-0.28 (-0.71, 0.15)		-0.06 (-0.43, 0.30)	
p-value [3]		0.204		0.728	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	78	
Mean (StdDev)	2.0 (0.95)	1.6 (1.11)	2.3 (1.19)	2.3 (1.23)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	-0.04 (0.289)	-0.58 (0.190)	-0.81 (0.177)	-0.67 (0.146)	
95% CI [2]	-0.61, 0.54	-0.96, -0.20	-1.16, -0.46	-0.96, -0.38	
Difference (95% CI) in CFB [2]		-0.54 (-1.15, 0.07)		0.14 (-0.28, 0.55)	
p-value [3]		0.081		0.516	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	2.0 (0.92)	1.8 (1.06)	2.6 (1.19)	2.3 (1.27)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	0.09 (0.333)	-0.46 (0.227)	-0.62 (0.194)	-0.70 (0.149)	
95% CI [2]	-0.58, 0.75	-0.92, -0.01	-1.00, -0.23	-0.99, -0.40	
Difference (95% CI) in CFB [2]		-0.55 (-1.24, 0.15)		-0.08 (-0.52, 0.36)	
p-value [3]		0.120		0.724	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	44	41	78	
Mean (StdDev)	2.0 (1.07)	1.6 (1.11)	2.7 (1.05)	2.5 (1.18)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	21	41	41	76	
LS Mean (StdErr) [2]	-0.13 (0.277)	-0.55 (0.197)	-0.38 (0.183)	-0.57 (0.145)	
95% CI [2]	-0.68, 0.43	-0.94, -0.16	-0.75, -0.02	-0.85, -0.28	
Difference (95% CI) in CFB [2]		-0.42 (-1.01, 0.16)		-0.19 (-0.61, 0.24)	
p-value [3]		0.154		0.389	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	2.2 (1.17)	1.6 (1.08)	2.6 (1.19)	2.3 (1.22)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	0.24 (0.274)	-0.49 (0.187)	-0.55 (0.202)	-0.67 (0.156)	
95% CI [2]	-0.31, 0.79	-0.86, -0.12	-0.95, -0.15	-0.98, -0.36	
Difference (95% CI) in CFB [2]		-0.73 (-1.30, -0.15)		-0.12 (-0.58, 0.35)	
p-value [3]		0.014		0.621	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	2.1 (1.21)	1.8 (1.17)	2.3 (1.15)	2.3 (1.18)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	0.32 (0.241)	-0.08 (0.166)	-0.82 (0.197)	-0.78 (0.156)	
95% CI [2]	-0.16, 0.80	-0.41, 0.26	-1.21, -0.43	-1.09, -0.47	
Difference (95% CI) in CFB [2]		-0.40 (-0.90, 0.10)		0.04 (-0.41, 0.49)	
Hedges'G (95% CI) in CFB		-0.36 (-0.91, 0.17)		0.03 (-0.36, 0.42)	
p-value [3]		0.116		0.867	
					0.269

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	1.6 (0.71)	2.1 (1.08)	2.6 (1.19)	2.9 (1.02)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	43	85	
Mean (StdDev)	1.8 (0.90)	1.6 (0.97)	2.2 (1.32)	2.3 (1.16)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	23	48	42	83	
LS Mean (StdErr) [2]	0.44 (0.208)	-0.31 (0.142)	-0.40 (0.148)	-0.67 (0.119)	
95% CI [2]	0.03, 0.86	-0.59, -0.03	-0.70, -0.11	-0.90, -0.43	
Difference (95% CI) in CFB [2]		-0.75 (-1.19, -0.32)		-0.26 (-0.60, 0.08)	
p-value [3]		<0.001		0.133	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	78	
Mean (StdDev)	1.6 (1.10)	1.4 (0.94)	2.3 (1.21)	2.1 (1.17)	
Median	1.5	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	0.20 (0.227)	-0.48 (0.149)	-0.29 (0.138)	-0.75 (0.114)	
95% CI [2]	-0.25, 0.65	-0.78, -0.18	-0.56, -0.01	-0.97, -0.52	
Difference (95% CI) in CFB [2]		-0.68 (-1.16, -0.20)		-0.46 (-0.78, -0.13)	
p-value [3]		0.006		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	1.4 (1.12)	1.4 (0.93)	2.3 (1.15)	2.2 (1.20)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	0.23 (0.223)	-0.46 (0.152)	-0.37 (0.175)	-0.67 (0.134)	
95% CI [2]	-0.22, 0.67	-0.76, -0.15	-0.71, -0.02	-0.93, -0.40	
Difference (95% CI) in CFB [2]		-0.68 (-1.15, -0.22)		-0.30 (-0.70, 0.10)	
p-value [3]		0.005		0.136	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	44	41	78	
Mean (StdDev)	1.6 (1.16)	1.4 (0.89)	2.3 (1.20)	2.1 (1.20)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	21	41	41	76	
LS Mean (StdErr) [2]	0.17 (0.215)	-0.39 (0.152)	-0.30 (0.182)	-0.80 (0.144)	
95% CI [2]	-0.26, 0.60	-0.70, -0.09	-0.66, 0.06	-1.08, -0.51	
Difference (95% CI) in CFB [2]		-0.56 (-1.02, -0.11)		-0.50 (-0.92, -0.08)	
p-value [3]		0.016		0.021	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	1.6 (1.24)	1.3 (0.94)	2.2 (1.18)	2.1 (1.26)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	0.12 (0.242)	-0.67 (0.166)	-0.49 (0.184)	-0.82 (0.143)	
95% CI [2]	-0.37, 0.60	-1.00, -0.33	-0.85, -0.12	-1.10, -0.54	
Difference (95% CI) in CFB [2]		-0.78 (-1.29, -0.27)		-0.33 (-0.75, 0.09)	
p-value [3]		0.003		0.124	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	1.5 (0.86)	1.4 (1.03)	2.3 (1.26)	1.9 (1.29)	
Median	1.5	1.0	3.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	0.18 (0.240)	-0.48 (0.166)	-0.32 (0.180)	-0.95 (0.143)	
95% CI [2]	-0.30, 0.67	-0.81, -0.14	-0.68, 0.04	-1.24, -0.67	
Difference (95% CI) in CFB [2]		-0.66 (-1.16, -0.16)		-0.64 (-1.05, -0.22)	
Hedges'G (95% CI) in CFB		-0.59 (-1.16, -0.07)		-0.52 (-0.93, -0.14)	
p-value [3]		0.011		0.003	
					0.936

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	1.6 (1.38)	1.7 (1.37)	2.2 (1.34)	2.3 (1.42)	
Median	2.0	2.0	2.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	1.2 (1.30)	1.2 (1.27)	1.9 (1.38)	1.8 (1.37)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	0.11 (0.325)	-0.19 (0.222)	-0.43 (0.221)	-0.60 (0.178)	
95% CI [2]	-0.54, 0.76	-0.63, 0.25	-0.87, 0.00	-0.95, -0.25	
Difference (95% CI) in CFB [2]		-0.31 (-0.99, 0.38)		-0.16 (-0.67, 0.35)	
p-value [3]		0.375		0.524	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	77	
Mean (StdDev)	1.5 (1.22)	1.2 (1.18)	1.8 (1.37)	1.7 (1.41)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	0.44 (0.329)	-0.16 (0.216)	-0.49 (0.230)	-0.69 (0.190)	
95% CI [2]	-0.22, 1.10	-0.60, 0.27	-0.94, -0.03	-1.07, -0.32	
Difference (95% CI) in CFB [2]		-0.60 (-1.30, 0.09)		-0.21 (-0.74, 0.33)	
p-value [3]		0.087		0.446	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	1.6 (1.32)	1.2 (1.12)	1.9 (1.19)	1.6 (1.37)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	0.54 (0.341)	-0.13 (0.232)	-0.45 (0.252)	-0.84 (0.194)	
95% CI [2]	-0.14, 1.22	-0.59, 0.34	-0.95, 0.05	-1.22, -0.46	
Difference (95% CI) in CFB [2]		-0.67 (-1.38, 0.04)		-0.39 (-0.96, 0.18)	
p-value [3]		0.065		0.183	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	40	78	
Mean (StdDev)	1.4 (1.16)	1.1 (1.10)	2.1 (1.22)	1.5 (1.36)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	21	42	40	76	
LS Mean (StdErr) [2]	0.16 (0.355)	-0.35 (0.251)	-0.28 (0.230)	-1.00 (0.181)	
95% CI [2]	-0.55, 0.87	-0.85, 0.16	-0.74, 0.18	-1.36, -0.64	
Difference (95% CI) in CFB [2]		-0.51 (-1.26, 0.24)		-0.72 (-1.25, -0.19)	
p-value [3]		0.178		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	1.6 (1.27)	1.1 (1.11)	2.0 (1.31)	1.6 (1.38)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	0.23 (0.272)	-0.39 (0.186)	-0.33 (0.256)	-0.77 (0.199)	
95% CI [2]	-0.31, 0.78	-0.77, -0.02	-0.84, 0.18	-1.16, -0.38	
Difference (95% CI) in CFB [2]		-0.63 (-1.20, -0.06)		-0.44 (-1.03, 0.15)	
p-value [3]		0.031		0.144	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	1.3 (1.21)	1.3 (1.16)	1.8 (1.35)	1.4 (1.36)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	-0.03 (0.252)	-0.27 (0.173)	-0.35 (0.258)	-0.85 (0.204)	
95% CI [2]	-0.53, 0.48	-0.61, 0.08	-0.86, 0.16	-1.26, -0.45	
Difference (95% CI) in CFB [2]		-0.24 (-0.77, 0.28)		-0.50 (-1.09, 0.08)	
Hedges'G (95% CI) in CFB		-0.21 (-0.75, 0.32)		-0.29 (-0.69, 0.09)	
p-value [3]		0.358		0.092	
					0.485

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	2.2 (1.41)	2.3 (1.28)	2.7 (1.14)	2.8 (1.28)	
Median	2.0	3.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	1.8 (1.21)	1.7 (1.31)	2.5 (1.17)	2.2 (1.31)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	-0.23 (0.274)	-0.43 (0.187)	-0.16 (0.186)	-0.57 (0.150)	
95% CI [2]	-0.78, 0.31	-0.80, -0.06	-0.53, 0.21	-0.87, -0.27	
Difference (95% CI) in CFB [2]		-0.20 (-0.77, 0.38)		-0.41 (-0.84, 0.02)	
p-value [3]		0.495		0.062	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	77	
Mean (StdDev)	2.0 (1.02)	1.5 (1.20)	2.4 (1.29)	2.0 (1.36)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	-0.03 (0.290)	-0.58 (0.190)	-0.29 (0.191)	-0.79 (0.157)	
95% CI [2]	-0.60, 0.55	-0.96, -0.20	-0.67, 0.09	-1.10, -0.48	
Difference (95% CI) in CFB [2]		-0.56 (-1.17, 0.05)		-0.50 (-0.94, -0.05)	
p-value [3]		0.072		0.029	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	1.6 (1.21)	1.7 (1.37)	2.4 (1.31)	2.1 (1.34)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	-0.37 (0.339)	-0.55 (0.231)	-0.28 (0.210)	-0.68 (0.161)	
95% CI [2]	-1.05, 0.31	-1.01, -0.09	-0.70, 0.13	-1.00, -0.36	
Difference (95% CI) in CFB [2]		-0.19 (-0.89, 0.52)		-0.40 (-0.87, 0.08)	
p-value [3]		0.603		0.100	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	40	78	
Mean (StdDev)	1.9 (1.20)	1.5 (1.06)	2.3 (1.22)	1.8 (1.32)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	21	42	40	76	
LS Mean (StdErr) [2]	-0.06 (0.331)	-0.73 (0.234)	-0.40 (0.200)	-0.97 (0.157)	
95% CI [2]	-0.72, 0.60	-1.20, -0.27	-0.80, -0.00	-1.28, -0.66	
Difference (95% CI) in CFB [2]		-0.68 (-1.37, 0.02)		-0.57 (-1.03, -0.11)	
p-value [3]		0.057		0.016	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	1.9 (1.20)	1.5 (1.20)	2.6 (1.27)	1.8 (1.36)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	-0.17 (0.311)	-0.74 (0.213)	-0.09 (0.207)	-0.84 (0.161)	
95% CI [2]	-0.79, 0.45	-1.17, -0.32	-0.50, 0.32	-1.15, -0.52	
Difference (95% CI) in CFB [2]		-0.57 (-1.23, 0.08)		-0.74 (-1.22, -0.26)	
p-value [3]		0.084		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	1.7 (1.32)	1.4 (1.24)	2.4 (1.23)	1.9 (1.38)	
Median	1.5	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	-0.31 (0.320)	-0.73 (0.220)	-0.27 (0.227)	-0.80 (0.179)	
95% CI [2]	-0.95, 0.32	-1.18, -0.29	-0.72, 0.18	-1.16, -0.45	
Difference (95% CI) in CFB [2]		-0.42 (-1.08, 0.24)		-0.54 (-1.06, -0.02)	
Hedges'G (95% CI) in CFB		-0.28 (-0.83, 0.25)		-0.35 (-0.75, 0.03)	
p-value [3]		0.211		0.042	
					0.728

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	2.1 (1.47)	1.9 (1.05)	2.5 (1.30)	2.7 (1.01)	
Median	2.5	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	1.8 (1.13)	1.4 (1.05)	2.2 (1.20)	2.1 (1.24)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	-0.07 (0.278)	-0.32 (0.190)	-0.21 (0.188)	-0.60 (0.152)	
95% CI [2]	-0.62, 0.49	-0.70, 0.05	-0.58, 0.16	-0.90, -0.30	
Difference (95% CI) in CFB [2]		-0.26 (-0.84, 0.33)		-0.39 (-0.83, 0.04)	
p-value [3]		0.384		0.075	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	77	
Mean (StdDev)	1.5 (1.06)	1.3 (1.07)	2.1 (1.47)	1.9 (1.12)	
Median	1.5	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	-0.28 (0.303)	-0.34 (0.199)	-0.33 (0.164)	-0.75 (0.135)	
95% CI [2]	-0.88, 0.33	-0.73, 0.06	-0.66, -0.01	-1.02, -0.48	
Difference (95% CI) in CFB [2]		-0.06 (-0.70, 0.58)		-0.42 (-0.80, -0.04)	
p-value [3]		0.847		0.032	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	1.5 (1.25)	1.3 (1.00)	2.3 (1.34)	2.0 (1.28)	
Median	1.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	-0.37 (0.311)	-0.44 (0.211)	-0.23 (0.218)	-0.77 (0.168)	
95% CI [2]	-0.99, 0.25	-0.86, -0.02	-0.66, 0.20	-1.10, -0.44	
Difference (95% CI) in CFB [2]		-0.07 (-0.72, 0.58)		-0.54 (-1.04, -0.05)	
p-value [3]		0.827		0.031	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	40	78	
Mean (StdDev)	1.7 (1.21)	1.2 (1.04)	2.2 (1.37)	1.8 (1.31)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	21	42	40	76	
LS Mean (StdErr) [2]	0.08 (0.320)	-0.49 (0.226)	-0.25 (0.210)	-0.94 (0.165)	
95% CI [2]	-0.56, 0.72	-0.94, -0.04	-0.67, 0.16	-1.27, -0.61	
Difference (95% CI) in CFB [2]		-0.57 (-1.24, 0.10)		-0.69 (-1.17, -0.20)	
p-value [3]		0.096		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	1.7 (1.14)	1.3 (1.12)	2.4 (1.39)	1.7 (1.28)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	0.12 (0.321)	-0.45 (0.219)	-0.02 (0.214)	-0.98 (0.166)	
95% CI [2]	-0.53, 0.76	-0.88, -0.01	-0.44, 0.41	-1.31, -0.65	
Difference (95% CI) in CFB [2]		-0.56 (-1.24, 0.11)		-0.97 (-1.46, -0.47)	
p-value [3]		0.101		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	1.6 (1.30)	1.3 (1.12)	2.2 (1.33)	1.9 (1.32)	
Median	2.0	1.0	2.5	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	0.00 (0.352)	-0.39 (0.243)	-0.21 (0.206)	-0.85 (0.163)	
95% CI [2]	-0.70, 0.70	-0.87, 0.10	-0.62, 0.20	-1.17, -0.53	
Difference (95% CI) in CFB [2]		-0.39 (-1.12, 0.34)		-0.64 (-1.11, -0.17)	
Hedges'G (95% CI) in CFB		-0.24 (-0.79, 0.29)		-0.46 (-0.86, -0.08)	
p-value [3]		0.293		0.008	
					0.476

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	1.8 (1.57)	1.6 (1.37)	1.7 (1.55)	2.0 (1.54)	
Median	1.5	1.0	1.5	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	1.4 (1.35)	1.3 (1.27)	2.0 (1.57)	1.6 (1.53)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	-0.24 (0.201)	-0.11 (0.137)	0.19 (0.187)	-0.36 (0.150)	
95% CI [2]	-0.64, 0.16	-0.39, 0.16	-0.17, 0.56	-0.65, -0.06	
Difference (95% CI) in CFB [2]		0.13 (-0.30, 0.55)		-0.55 (-0.98, -0.12)	
p-value [3]		0.554		0.013	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	77	
Mean (StdDev)	1.3 (1.24)	1.2 (1.31)	1.6 (1.68)	1.5 (1.45)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	-0.39 (0.243)	-0.16 (0.159)	-0.07 (0.183)	-0.50 (0.151)	
95% CI [2]	-0.87, 0.10	-0.47, 0.16	-0.43, 0.30	-0.80, -0.20	
Difference (95% CI) in CFB [2]		0.23 (-0.28, 0.74)		-0.44 (-0.86, -0.01)	
p-value [3]		0.373		0.045	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	1.2 (1.21)	1.2 (1.37)	1.8 (1.39)	1.4 (1.41)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	-0.36 (0.308)	-0.19 (0.209)	-0.06 (0.227)	-0.51 (0.174)	
95% CI [2]	-0.98, 0.25	-0.61, 0.23	-0.51, 0.39	-0.85, -0.16	
Difference (95% CI) in CFB [2]		0.17 (-0.47, 0.81)		-0.45 (-0.96, 0.07)	
p-value [3]		0.595		0.086	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	40	77	
Mean (StdDev)	1.1 (1.12)	1.2 (1.26)	1.6 (1.52)	1.3 (1.37)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	21	42	40	75	
LS Mean (StdErr) [2]	-0.27 (0.302)	-0.25 (0.213)	-0.11 (0.228)	-0.61 (0.180)	
95% CI [2]	-0.87, 0.34	-0.68, 0.18	-0.57, 0.34	-0.97, -0.26	
Difference (95% CI) in CFB [2]		0.02 (-0.62, 0.65)		-0.50 (-1.03, 0.03)	
p-value [3]		0.962		0.065	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	1.0 (1.15)	1.0 (1.24)	1.6 (1.48)	1.5 (1.50)	
Median	1.0	0.0	1.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	-0.42 (0.279)	-0.45 (0.191)	-0.08 (0.259)	-0.45 (0.201)	
95% CI [2]	-0.98, 0.13	-0.83, -0.06	-0.60, 0.43	-0.84, -0.05	
Difference (95% CI) in CFB [2]		-0.02 (-0.61, 0.56)		-0.36 (-0.96, 0.24)	
p-value [3]		0.943		0.233	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	1.2 (1.11)	1.3 (1.31)	1.6 (1.55)	1.4 (1.48)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	-0.26 (0.258)	-0.16 (0.178)	0.04 (0.248)	-0.48 (0.196)	
95% CI [2]	-0.78, 0.25	-0.52, 0.19	-0.45, 0.53	-0.87, -0.09	
Difference (95% CI) in CFB [2]		0.10 (-0.44, 0.64)		-0.52 (-1.08, 0.05)	
Hedges'G (95% CI) in CFB		0.08 (-0.45, 0.62)		-0.31 (-0.71, 0.07)	
p-value [3]		0.711		0.074	
					0.142

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	2.0 (1.33)	1.9 (1.18)	2.3 (1.27)	2.6 (1.12)	
Median	2.0	2.0	2.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	1.8 (1.23)	1.5 (1.11)	1.8 (1.23)	2.0 (1.21)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	-0.36 (0.214)	-0.52 (0.146)	-0.42 (0.148)	-0.48 (0.120)	
95% CI [2]	-0.79, 0.07	-0.81, -0.23	-0.71, -0.12	-0.72, -0.25	
Difference (95% CI) in CFB [2]		-0.16 (-0.61, 0.28)		-0.07 (-0.41, 0.27)	
p-value [3]		0.468		0.696	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	77	
Mean (StdDev)	1.7 (1.20)	1.2 (1.08)	2.0 (1.33)	1.8 (1.32)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	-0.25 (0.264)	-0.75 (0.173)	-0.26 (0.162)	-0.69 (0.134)	
95% CI [2]	-0.78, 0.28	-1.10, -0.41	-0.58, 0.06	-0.96, -0.43	
Difference (95% CI) in CFB [2]		-0.50 (-1.06, 0.05)		-0.43 (-0.81, -0.06)	
p-value [3]		0.075		0.025	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	1.6 (1.33)	1.3 (1.07)	2.0 (1.08)	1.6 (1.25)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	-0.26 (0.265)	-0.50 (0.180)	-0.33 (0.166)	-0.91 (0.128)	
95% CI [2]	-0.79, 0.27	-0.86, -0.14	-0.66, -0.00	-1.16, -0.66	
Difference (95% CI) in CFB [2]		-0.24 (-0.79, 0.31)		-0.57 (-0.95, -0.20)	
p-value [3]		0.390		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	40	78	
Mean (StdDev)	1.5 (1.20)	1.0 (0.90)	1.9 (1.22)	1.7 (1.31)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	21	42	40	76	
LS Mean (StdErr) [2]	-0.45 (0.299)	-1.12 (0.212)	-0.40 (0.172)	-0.81 (0.135)	
95% CI [2]	-1.05, 0.15	-1.55, -0.70	-0.74, -0.05	-1.07, -0.54	
Difference (95% CI) in CFB [2]		-0.67 (-1.30, -0.04)		-0.41 (-0.81, -0.01)	
p-value [3]		0.038		0.044	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	1.7 (1.11)	1.2 (1.21)	2.2 (1.25)	1.7 (1.36)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	-0.29 (0.269)	-0.84 (0.184)	-0.02 (0.194)	-0.79 (0.151)	
95% CI [2]	-0.82, 0.25	-1.21, -0.48	-0.41, 0.36	-1.09, -0.49	
Difference (95% CI) in CFB [2]		-0.56 (-1.12, 0.01)		-0.77 (-1.22, -0.32)	
p-value [3]		0.052		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	1.5 (1.34)	1.1 (1.08)	2.1 (1.36)	1.7 (1.39)	
Median	1.5	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	-0.28 (0.266)	-0.72 (0.183)	-0.13 (0.187)	-0.78 (0.148)	
95% CI [2]	-0.81, 0.25	-1.09, -0.36	-0.50, 0.24	-1.07, -0.49	
Difference (95% CI) in CFB [2]		-0.44 (-1.00, 0.11)		-0.65 (-1.07, -0.22)	
Hedges'G (95% CI) in CFB		-0.36 (-0.91, 0.17)		-0.52 (-0.92, -0.13)	
p-value [3]		0.113		0.003	
					0.545

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	1.6 (1.53)	1.6 (1.21)	2.1 (1.31)	2.4 (1.27)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	1.3 (1.22)	1.2 (1.20)	1.5 (1.19)	1.8 (1.26)	
Median	1.0	1.0	1.0	2.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	-0.25 (0.221)	-0.33 (0.150)	-0.52 (0.173)	-0.55 (0.140)	
95% CI [2]	-0.69, 0.19	-0.63, -0.03	-0.86, -0.17	-0.83, -0.28	
Difference (95% CI) in CFB [2]		-0.08 (-0.54, 0.39)		-0.04 (-0.44, 0.36)	
p-value [3]		0.747		0.852	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	77	
Mean (StdDev)	1.3 (1.25)	1.1 (1.13)	1.7 (1.29)	1.6 (1.33)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	-0.22 (0.230)	-0.44 (0.151)	-0.36 (0.172)	-0.74 (0.142)	
95% CI [2]	-0.68, 0.24	-0.74, -0.14	-0.70, -0.02	-1.02, -0.46	
Difference (95% CI) in CFB [2]		-0.22 (-0.70, 0.27)		-0.38 (-0.78, 0.02)	
p-value [3]		0.378		0.065	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	1.4 (1.33)	1.0 (0.97)	1.7 (1.06)	1.5 (1.33)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	-0.20 (0.230)	-0.61 (0.157)	-0.55 (0.186)	-0.83 (0.143)	
95% CI [2]	-0.66, 0.26	-0.92, -0.30	-0.92, -0.18	-1.11, -0.54	
Difference (95% CI) in CFB [2]		-0.41 (-0.89, 0.07)		-0.28 (-0.70, 0.14)	
p-value [3]		0.092		0.192	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	40	78	
Mean (StdDev)	1.3 (1.36)	0.9 (0.97)	1.7 (1.27)	1.5 (1.29)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	21	42	40	76	
LS Mean (StdErr) [2]	0.01 (0.294)	-0.71 (0.208)	-0.53 (0.185)	-0.90 (0.145)	
95% CI [2]	-0.58, 0.60	-1.13, -0.30	-0.90, -0.16	-1.19, -0.61	
Difference (95% CI) in CFB [2]		-0.72 (-1.34, -0.10)		-0.37 (-0.80, 0.06)	
p-value [3]		0.023		0.088	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	1.3 (1.27)	0.9 (1.02)	1.8 (1.25)	1.6 (1.41)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	-0.11 (0.242)	-0.70 (0.166)	-0.30 (0.202)	-0.87 (0.157)	
95% CI [2]	-0.59, 0.38	-1.03, -0.37	-0.70, 0.10	-1.18, -0.56	
Difference (95% CI) in CFB [2]		-0.59 (-1.10, -0.08)		-0.57 (-1.03, -0.10)	
p-value [3]		0.024		0.018	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	1.2 (1.26)	0.9 (1.10)	1.7 (1.34)	1.4 (1.42)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	-0.14 (0.250)	-0.58 (0.172)	-0.24 (0.199)	-0.78 (0.157)	
95% CI [2]	-0.64, 0.36	-0.93, -0.24	-0.63, 0.16	-1.09, -0.47	
Difference (95% CI) in CFB [2]		-0.44 (-0.96, 0.07)		-0.55 (-1.00, -0.09)	
Hedges'G (95% CI) in CFB		-0.38 (-0.94, 0.14)		-0.41 (-0.81, -0.03)	
p-value [3]		0.092		0.018	
					0.785

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	2.8 (0.93)	2.5 (1.12)	3.1 (0.94)	3.1 (0.93)	
Median	3.0	3.0	3.0	3.0	
Min, Max	1, 4	0, 4	0, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	2.4 (1.04)	2.1 (0.94)	2.6 (1.09)	2.7 (1.02)	
Median	3.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	-0.54 (0.216)	-0.48 (0.147)	-0.49 (0.151)	-0.40 (0.122)	
95% CI [2]	-0.97, -0.11	-0.78, -0.19	-0.78, -0.19	-0.64, -0.16	
Difference (95% CI) in CFB [2]		0.05 (-0.40, 0.51)		0.09 (-0.26, 0.43)	
p-value [3]		0.815		0.627	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	77	
Mean (StdDev)	2.5 (0.91)	1.9 (1.08)	2.6 (1.16)	2.4 (1.15)	
Median	3.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	-0.17 (0.232)	-0.49 (0.152)	-0.46 (0.162)	-0.62 (0.134)	
95% CI [2]	-0.64, 0.29	-0.79, -0.18	-0.78, -0.14	-0.89, -0.36	
Difference (95% CI) in CFB [2]		-0.31 (-0.80, 0.17)		-0.16 (-0.54, 0.21)	
p-value [3]		0.203		0.391	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	2.1 (1.28)	2.0 (1.15)	2.5 (1.23)	2.4 (1.24)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	-0.60 (0.290)	-0.38 (0.198)	-0.55 (0.179)	-0.52 (0.138)	
95% CI [2]	-1.18, -0.02	-0.78, 0.01	-0.91, -0.20	-0.80, -0.25	
Difference (95% CI) in CFB [2]		0.22 (-0.39, 0.83)		0.03 (-0.38, 0.43)	
p-value [3]		0.472		0.892	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	41	78	
Mean (StdDev)	2.0 (1.09)	1.8 (1.20)	2.7 (1.00)	2.2 (1.31)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C5D1 CFB					
n	21	42	41	76	
LS Mean (StdErr) [2]	-0.89 (0.313)	-0.79 (0.221)	-0.36 (0.188)	-0.87 (0.149)	
95% CI [2]	-1.51, -0.26	-1.24, -0.35	-0.73, 0.01	-1.17, -0.58	
Difference (95% CI) in CFB [2]		0.09 (-0.56, 0.75)		-0.51 (-0.95, -0.08)	
p-value [3]		0.774		0.021	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	2.3 (0.92)	1.8 (1.14)	2.6 (1.35)	2.3 (1.29)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	-0.36 (0.236)	-0.61 (0.161)	-0.31 (0.213)	-0.67 (0.166)	
95% CI [2]	-0.83, 0.11	-0.93, -0.28	-0.73, 0.11	-0.99, -0.34	
Difference (95% CI) in CFB [2]		-0.25 (-0.75, 0.24)		-0.36 (-0.85, 0.13)	
p-value [3]		0.316		0.153	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	2.3 (0.98)	1.8 (0.93)	2.6 (1.20)	2.3 (1.27)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	-0.37 (0.299)	-0.57 (0.206)	-0.43 (0.187)	-0.68 (0.147)	
95% CI [2]	-0.97, 0.23	-0.98, -0.15	-0.80, -0.06	-0.97, -0.39	
Difference (95% CI) in CFB [2]		-0.20 (-0.82, 0.42)		-0.25 (-0.68, 0.17)	
Hedges'G (95% CI) in CFB		-0.14 (-0.69, 0.39)		-0.20 (-0.60, 0.18)	
p-value [3]		0.523		0.240	
					0.876

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	2.2 (1.64)	2.4 (1.08)	2.5 (1.39)	2.5 (1.28)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	1.8 (1.47)	1.8 (1.20)	2.4 (1.10)	2.1 (1.39)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	-0.57 (0.241)	-0.70 (0.165)	-0.13 (0.171)	-0.36 (0.138)	
95% CI [2]	-1.06, -0.09	-1.02, -0.37	-0.47, 0.21	-0.64, -0.09	
Difference (95% CI) in CFB [2]		-0.12 (-0.63, 0.38)		-0.24 (-0.63, 0.16)	
p-value [3]		0.634		0.239	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	77	
Mean (StdDev)	2.0 (1.38)	1.6 (1.16)	2.4 (1.19)	1.9 (1.33)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	-0.38 (0.282)	-0.92 (0.185)	-0.10 (0.186)	-0.48 (0.153)	
95% CI [2]	-0.94, 0.18	-1.29, -0.55	-0.46, 0.27	-0.78, -0.18	
Difference (95% CI) in CFB [2]		-0.54 (-1.13, 0.06)		-0.39 (-0.82, 0.05)	
p-value [3]		0.076		0.081	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	1.5 (1.54)	1.5 (1.30)	2.3 (1.18)	2.0 (1.41)	
Median	1.0	1.5	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	-0.61 (0.284)	-0.78 (0.194)	-0.11 (0.180)	-0.42 (0.138)	
95% CI [2]	-1.18, -0.04	-1.17, -0.39	-0.47, 0.25	-0.70, -0.15	
Difference (95% CI) in CFB [2]		-0.17 (-0.77, 0.42)		-0.31 (-0.72, 0.09)	
p-value [3]		0.567		0.128	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	41	78	
Mean (StdDev)	1.7 (1.64)	1.6 (1.32)	2.1 (1.40)	1.8 (1.49)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	21	42	41	76	
LS Mean (StdErr) [2]	-0.50 (0.299)	-0.82 (0.211)	-0.39 (0.186)	-0.72 (0.147)	
95% CI [2]	-1.10, 0.10	-1.24, -0.39	-0.76, -0.02	-1.01, -0.43	
Difference (95% CI) in CFB [2]		-0.32 (-0.95, 0.31)		-0.33 (-0.76, 0.10)	
p-value [3]		0.317		0.130	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	1.9 (1.52)	1.4 (1.19)	2.4 (1.21)	1.8 (1.44)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	-0.33 (0.244)	-1.07 (0.167)	-0.06 (0.202)	-0.65 (0.157)	
95% CI [2]	-0.82, 0.16	-1.41, -0.74	-0.46, 0.34	-0.96, -0.34	
Difference (95% CI) in CFB [2]		-0.75 (-1.26, -0.23)		-0.59 (-1.06, -0.13)	
p-value [3]		0.005		0.013	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	1.8 (1.69)	1.3 (1.34)	2.2 (1.32)	1.6 (1.44)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	-0.39 (0.274)	-1.00 (0.189)	-0.31 (0.212)	-0.74 (0.167)	
95% CI [2]	-0.94, 0.16	-1.38, -0.62	-0.73, 0.11	-1.07, -0.41	
Difference (95% CI) in CFB [2]		-0.61 (-1.18, -0.04)		-0.43 (-0.92, 0.05)	
Hedges'G (95% CI) in CFB		-0.48 (-1.04, 0.05)		-0.30 (-0.70, 0.08)	
p-value [3]		0.037		0.079	
					0.633

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	2.7 (1.24)	2.6 (1.00)	2.9 (1.06)	3.1 (0.95)	
Median	3.0	3.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	2.3 (1.17)	1.7 (1.21)	2.3 (1.10)	2.5 (1.17)	
Median	2.0	2.0	2.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	-0.40 (0.246)	-0.82 (0.168)	-0.66 (0.153)	-0.62 (0.124)	
95% CI [2]	-0.89, 0.09	-1.16, -0.48	-0.97, -0.36	-0.87, -0.38	
Difference (95% CI) in CFB [2]		-0.42 (-0.93, 0.10)		0.04 (-0.31, 0.39)	
p-value [3]		0.112		0.825	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	77	
Mean (StdDev)	2.4 (1.10)	1.7 (1.07)	2.4 (1.25)	2.2 (1.24)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	-0.41 (0.285)	-0.90 (0.187)	-0.43 (0.166)	-0.87 (0.137)	
95% CI [2]	-0.98, 0.16	-1.28, -0.53	-0.76, -0.10	-1.14, -0.60	
Difference (95% CI) in CFB [2]		-0.49 (-1.09, 0.11)		-0.44 (-0.83, -0.06)	
p-value [3]		0.109		0.025	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	2.3 (1.20)	1.8 (1.12)	2.5 (1.14)	2.2 (1.29)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	-0.45 (0.289)	-0.80 (0.197)	-0.40 (0.183)	-0.96 (0.140)	
95% CI [2]	-1.02, 0.13	-1.20, -0.41	-0.76, -0.04	-1.24, -0.68	
Difference (95% CI) in CFB [2]		-0.36 (-0.96, 0.25)		-0.56 (-0.97, -0.15)	
p-value [3]		0.241		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	41	77	
Mean (StdDev)	2.3 (1.29)	1.6 (1.00)	2.3 (1.13)	2.1 (1.26)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	21	42	41	75	
LS Mean (StdErr) [2]	-0.17 (0.292)	-0.92 (0.207)	-0.63 (0.170)	-1.03 (0.135)	
95% CI [2]	-0.75, 0.42	-1.33, -0.50	-0.97, -0.30	-1.29, -0.76	
Difference (95% CI) in CFB [2]		-0.75 (-1.36, -0.13)		-0.39 (-0.79, -0.00)	
p-value [3]		0.018		0.050	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	2.6 (1.12)	1.6 (1.09)	2.4 (1.18)	2.0 (1.40)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	0.06 (0.279)	-1.00 (0.191)	-0.57 (0.193)	-1.14 (0.150)	
95% CI [2]	-0.50, 0.62	-1.38, -0.62	-0.95, -0.19	-1.43, -0.84	
Difference (95% CI) in CFB [2]		-1.06 (-1.65, -0.48)		-0.56 (-1.01, -0.12)	
p-value [3]		<0.001		0.014	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	2.3 (1.35)	1.7 (1.13)	2.3 (1.30)	2.0 (1.38)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	-0.36 (0.290)	-0.86 (0.200)	-0.50 (0.190)	-1.00 (0.150)	
95% CI [2]	-0.95, 0.22	-1.26, -0.46	-0.87, -0.12	-1.29, -0.70	
Difference (95% CI) in CFB [2]		-0.50 (-1.10, 0.11)		-0.50 (-0.93, -0.06)	
Hedges'G (95% CI) in CFB		-0.37 (-0.92, 0.16)		-0.39 (-0.79, -0.01)	
p-value [3]		0.104		0.025	
					0.975

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	2.8 (1.11)	2.8 (0.92)	3.2 (0.77)	3.2 (0.96)	
Median	3.0	3.0	3.0	3.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	2.3 (1.02)	2.1 (1.11)	2.8 (0.94)	2.4 (1.07)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	-0.26 (0.234)	-0.57 (0.160)	-0.50 (0.150)	-0.81 (0.121)	
95% CI [2]	-0.72, 0.21	-0.89, -0.25	-0.80, -0.20	-1.05, -0.57	
Difference (95% CI) in CFB [2]		-0.31 (-0.80, 0.18)		-0.32 (-0.66, 0.03)	
p-value [3]		0.206		0.074	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	77	
Mean (StdDev)	2.4 (1.05)	1.8 (1.23)	2.5 (1.12)	2.3 (1.12)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	-0.08 (0.312)	-0.84 (0.204)	-0.69 (0.161)	-0.98 (0.133)	
95% CI [2]	-0.70, 0.54	-1.25, -0.43	-1.00, -0.37	-1.24, -0.71	
Difference (95% CI) in CFB [2]		-0.76 (-1.42, -0.11)		-0.29 (-0.66, 0.09)	
p-value [3]		0.024		0.129	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	2.2 (1.33)	1.6 (1.09)	2.6 (1.05)	2.3 (1.10)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	-0.39 (0.308)	-1.07 (0.210)	-0.64 (0.168)	-0.96 (0.129)	
95% CI [2]	-1.00, 0.23	-1.49, -0.65	-0.97, -0.30	-1.21, -0.70	
Difference (95% CI) in CFB [2]		-0.68 (-1.32, -0.04)		-0.32 (-0.70, 0.06)	
p-value [3]		0.039		0.098	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	41	78	
Mean (StdDev)	2.2 (1.31)	1.8 (1.06)	2.4 (1.29)	2.3 (1.22)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	21	42	41	76	
LS Mean (StdErr) [2]	-0.28 (0.321)	-0.94 (0.227)	-0.76 (0.180)	-1.04 (0.142)	
95% CI [2]	-0.92, 0.36	-1.40, -0.49	-1.11, -0.40	-1.32, -0.76	
Difference (95% CI) in CFB [2]		-0.66 (-1.34, 0.01)		-0.28 (-0.70, 0.13)	
p-value [3]		0.054		0.181	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	2.5 (1.08)	1.7 (1.04)	2.6 (1.19)	2.1 (1.36)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	-0.17 (0.279)	-1.07 (0.191)	-0.62 (0.201)	-1.12 (0.156)	
95% CI [2]	-0.73, 0.39	-1.45, -0.68	-1.02, -0.22	-1.43, -0.81	
Difference (95% CI) in CFB [2]		-0.89 (-1.48, -0.31)		-0.50 (-0.96, -0.03)	
p-value [3]		0.003		0.036	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	2.2 (1.44)	1.8 (1.07)	2.4 (1.28)	2.1 (1.34)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	-0.37 (0.298)	-0.86 (0.205)	-0.70 (0.201)	-1.14 (0.159)	
95% CI [2]	-0.96, 0.23	-1.27, -0.45	-1.09, -0.30	-1.46, -0.83	
Difference (95% CI) in CFB [2]		-0.50 (-1.11, 0.12)		-0.45 (-0.90, 0.01)	
Hedges'G (95% CI) in CFB		-0.36 (-0.91, 0.17)		-0.33 (-0.73, 0.05)	
p-value [3]		0.115		0.057	
					0.928

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	1.9 (1.57)	1.1 (1.19)	2.4 (1.43)	2.2 (1.45)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	1.6 (1.41)	0.9 (1.08)	2.0 (1.43)	1.7 (1.48)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	0.15 (0.255)	-0.04 (0.174)	-0.15 (0.195)	-0.31 (0.158)	
95% CI [2]	-0.36, 0.66	-0.39, 0.31	-0.53, 0.24	-0.63, -0.00	
Difference (95% CI) in CFB [2]		-0.19 (-0.72, 0.35)		-0.17 (-0.62, 0.28)	
p-value [3]		0.486		0.463	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	77	
Mean (StdDev)	1.7 (1.32)	0.8 (0.97)	2.0 (1.43)	1.6 (1.49)	
Median	1.5	0.5	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	0.15 (0.306)	-0.13 (0.201)	-0.23 (0.207)	-0.57 (0.171)	
95% CI [2]	-0.46, 0.77	-0.53, 0.27	-0.64, 0.18	-0.91, -0.24	
Difference (95% CI) in CFB [2]		-0.28 (-0.93, 0.36)		-0.34 (-0.82, 0.14)	
p-value [3]		0.385		0.165	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	1.5 (1.21)	0.8 (1.08)	2.0 (1.31)	1.8 (1.43)	
Median	1.0	0.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	-0.04 (0.303)	-0.09 (0.207)	-0.29 (0.205)	-0.41 (0.158)	
95% CI [2]	-0.65, 0.57	-0.50, 0.33	-0.70, 0.12	-0.72, -0.10	
Difference (95% CI) in CFB [2]		-0.05 (-0.68, 0.58)		-0.12 (-0.59, 0.34)	
p-value [3]		0.877		0.600	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	41	78	
Mean (StdDev)	1.4 (1.27)	0.8 (1.09)	2.0 (1.37)	1.7 (1.43)	
Median	1.0	0.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	21	42	41	76	
LS Mean (StdErr) [2]	-0.05 (0.292)	-0.05 (0.206)	-0.26 (0.231)	-0.48 (0.183)	
95% CI [2]	-0.63, 0.54	-0.46, 0.36	-0.71, 0.20	-0.84, -0.12	
Difference (95% CI) in CFB [2]		-0.00 (-0.62, 0.61)		-0.23 (-0.76, 0.31)	
p-value [3]		0.992		0.402	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	1.7 (1.34)	0.8 (1.07)	1.9 (1.52)	1.6 (1.36)	
Median	2.0	0.5	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	0.12 (0.290)	-0.11 (0.198)	-0.43 (0.243)	-0.64 (0.189)	
95% CI [2]	-0.46, 0.70	-0.51, 0.29	-0.91, 0.05	-1.01, -0.27	
Difference (95% CI) in CFB [2]		-0.23 (-0.84, 0.38)		-0.21 (-0.77, 0.35)	
p-value [3]		0.458		0.465	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	1.7 (1.42)	1.0 (1.11)	2.0 (1.54)	1.4 (1.40)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	0.23 (0.294)	-0.03 (0.202)	-0.16 (0.243)	-0.57 (0.192)	
95% CI [2]	-0.36, 0.82	-0.44, 0.37	-0.65, 0.32	-0.95, -0.19	
Difference (95% CI) in CFB [2]		-0.26 (-0.87, 0.35)		-0.41 (-0.96, 0.15)	
Hedges'G (95% CI) in CFB		-0.19 (-0.74, 0.34)		-0.25 (-0.64, 0.13)	
p-value [3]		0.390		0.148	
					0.736

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	1.0 (0.98)	1.4 (1.09)	2.0 (1.24)	1.9 (1.39)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	1.0 (1.10)	1.0 (0.90)	1.7 (1.04)	1.5 (1.38)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 3	0, 4	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	-0.16 (0.202)	-0.40 (0.138)	-0.39 (0.140)	-0.50 (0.113)	
95% CI [2]	-0.57, 0.24	-0.68, -0.13	-0.67, -0.11	-0.72, -0.28	
Difference (95% CI) in CFB [2]		-0.24 (-0.67, 0.18)		-0.11 (-0.43, 0.21)	
p-value [3]		0.262		0.502	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	77	
Mean (StdDev)	1.1 (1.11)	0.7 (0.74)	1.7 (1.17)	1.3 (1.34)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 2	0, 4	0, 4	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	0.10 (0.281)	-0.67 (0.184)	-0.49 (0.176)	-0.76 (0.145)	
95% CI [2]	-0.46, 0.66	-1.04, -0.30	-0.83, -0.14	-1.05, -0.47	
Difference (95% CI) in CFB [2]		-0.77 (-1.36, -0.18)		-0.27 (-0.68, 0.14)	
p-value [3]		0.012		0.191	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	1.2 (1.26)	0.7 (0.82)	1.7 (1.13)	1.3 (1.27)	
Median	1.0	0.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	0.21 (0.265)	-0.71 (0.181)	-0.48 (0.200)	-0.73 (0.154)	
95% CI [2]	-0.32, 0.74	-1.07, -0.35	-0.87, -0.08	-1.04, -0.43	
Difference (95% CI) in CFB [2]		-0.91 (-1.47, -0.36)		-0.26 (-0.71, 0.19)	
p-value [3]		0.002		0.261	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	41	78	
Mean (StdDev)	1.1 (1.18)	0.6 (0.76)	1.7 (1.11)	1.3 (1.30)	
Median	1.0	0.0	1.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	21	42	41	76	
LS Mean (StdErr) [2]	0.09 (0.250)	-0.79 (0.177)	-0.55 (0.183)	-0.81 (0.145)	
95% CI [2]	-0.41, 0.59	-1.14, -0.44	-0.91, -0.19	-1.10, -0.52	
Difference (95% CI) in CFB [2]		-0.88 (-1.41, -0.35)		-0.26 (-0.68, 0.16)	
p-value [3]		0.001		0.228	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	1.2 (1.03)	0.7 (0.90)	1.7 (1.22)	1.3 (1.26)	
Median	1.0	0.0	2.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	0.24 (0.259)	-0.61 (0.177)	-0.54 (0.181)	-0.77 (0.141)	
95% CI [2]	-0.28, 0.75	-0.97, -0.26	-0.89, -0.18	-1.05, -0.49	
Difference (95% CI) in CFB [2]		-0.85 (-1.39, -0.30)		-0.23 (-0.65, 0.18)	
p-value [3]		0.003		0.271	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	1.0 (1.00)	0.7 (0.84)	1.5 (1.15)	1.1 (1.25)	
Median	1.0	0.5	1.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	0.12 (0.255)	-0.51 (0.176)	-0.64 (0.184)	-0.80 (0.145)	
95% CI [2]	-0.39, 0.63	-0.87, -0.16	-1.01, -0.28	-1.09, -0.51	
Difference (95% CI) in CFB [2]		-0.64 (-1.17, -0.11)		-0.15 (-0.57, 0.27)	
Hedges'G (95% CI) in CFB		-0.54 (-1.10, -0.01)		-0.12 (-0.51, 0.26)	
p-value [3]		0.019		0.473	
					0.220

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	0.8 (1.10)	0.8 (1.11)	1.4 (1.32)	1.7 (1.53)	
Median	0.0	0.0	1.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	0.8 (1.28)	0.8 (1.13)	1.3 (1.34)	1.4 (1.42)	
Median	0.0	0.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	-0.07 (0.247)	-0.10 (0.169)	-0.05 (0.167)	-0.24 (0.135)	
95% CI [2]	-0.56, 0.42	-0.43, 0.24	-0.39, 0.28	-0.51, 0.02	
Difference (95% CI) in CFB [2]		-0.02 (-0.54, 0.49)		-0.19 (-0.58, 0.20)	
p-value [3]		0.924		0.331	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	77	
Mean (StdDev)	0.5 (0.86)	0.6 (0.96)	1.2 (1.27)	1.1 (1.30)	
Median	0.0	0.0	1.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	-0.16 (0.238)	-0.12 (0.156)	-0.20 (0.191)	-0.62 (0.158)	
95% CI [2]	-0.63, 0.32	-0.43, 0.19	-0.58, 0.18	-0.93, -0.30	
Difference (95% CI) in CFB [2]		0.04 (-0.46, 0.54)		-0.42 (-0.86, 0.03)	
p-value [3]		0.882		0.067	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	1.0 (1.07)	0.5 (0.75)	1.4 (1.35)	1.2 (1.33)	
Median	1.0	0.0	1.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	0.13 (0.254)	-0.49 (0.173)	-0.17 (0.204)	-0.57 (0.157)	
95% CI [2]	-0.38, 0.64	-0.83, -0.14	-0.58, 0.23	-0.88, -0.26	
Difference (95% CI) in CFB [2]		-0.62 (-1.15, -0.09)		-0.40 (-0.86, 0.06)	
p-value [3]		0.024		0.087	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	41	78	
Mean (StdDev)	0.7 (1.02)	0.3 (0.56)	1.4 (1.30)	1.2 (1.35)	
Median	0.0	0.0	1.0	1.0	
Min, Max	0, 4	0, 2	0, 4	0, 4	
C5D1 CFB					
n	21	42	41	76	
LS Mean (StdErr) [2]	0.06 (0.198)	-0.47 (0.140)	-0.13 (0.193)	-0.58 (0.152)	
95% CI [2]	-0.34, 0.45	-0.75, -0.19	-0.51, 0.25	-0.88, -0.27	
Difference (95% CI) in CFB [2]		-0.53 (-0.94, -0.11)		-0.45 (-0.89, 0.00)	
p-value [3]		0.014		0.050	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	0.8 (0.98)	0.4 (0.74)	1.4 (1.33)	1.2 (1.28)	
Median	1.0	0.0	1.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	0.05 (0.200)	-0.47 (0.137)	-0.20 (0.205)	-0.64 (0.159)	
95% CI [2]	-0.35, 0.45	-0.74, -0.19	-0.61, 0.21	-0.96, -0.33	
Difference (95% CI) in CFB [2]		-0.51 (-0.93, -0.09)		-0.44 (-0.92, 0.03)	
p-value [3]		0.017		0.066	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	0.7 (0.94)	0.5 (0.82)	1.3 (1.26)	1.1 (1.36)	
Median	0.0	0.0	1.0	0.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	0.13 (0.225)	-0.16 (0.155)	-0.16 (0.198)	-0.61 (0.156)	
95% CI [2]	-0.32, 0.58	-0.47, 0.15	-0.55, 0.23	-0.92, -0.30	
Difference (95% CI) in CFB [2]		-0.29 (-0.76, 0.17)		-0.45 (-0.90, -0.00)	
Hedges'G (95% CI) in CFB		-0.28 (-0.83, 0.25)		-0.34 (-0.74, 0.04)	
p-value [3]		0.215		0.050	
					0.628

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	1.5 (1.14)	1.3 (1.13)	2.2 (1.11)	2.2 (1.30)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	1.1 (1.04)	0.9 (1.01)	1.7 (1.33)	1.6 (1.30)	
Median	1.0	0.0	2.0	2.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	-0.47 (0.230)	-0.64 (0.157)	-0.54 (0.179)	-0.60 (0.144)	
95% CI [2]	-0.93, -0.01	-0.96, -0.33	-0.90, -0.19	-0.89, -0.32	
Difference (95% CI) in CFB [2]		-0.17 (-0.65, 0.31)		-0.06 (-0.47, 0.35)	
p-value [3]		0.481		0.778	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	77	
Mean (StdDev)	1.3 (1.03)	0.9 (1.00)	1.6 (1.15)	1.5 (1.13)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	-0.33 (0.248)	-0.56 (0.162)	-0.57 (0.162)	-0.72 (0.134)	
95% CI [2]	-0.83, 0.16	-0.88, -0.23	-0.89, -0.25	-0.99, -0.46	
Difference (95% CI) in CFB [2]		-0.22 (-0.74, 0.30)		-0.16 (-0.54, 0.22)	
p-value [3]		0.397		0.408	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	1.2 (1.18)	0.8 (0.99)	1.6 (1.27)	1.6 (1.23)	
Median	1.0	1.0	1.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	-0.38 (0.285)	-0.76 (0.194)	-0.46 (0.201)	-0.65 (0.155)	
95% CI [2]	-0.95, 0.19	-1.15, -0.38	-0.86, -0.06	-0.96, -0.34	
Difference (95% CI) in CFB [2]		-0.38 (-0.98, 0.21)		-0.19 (-0.65, 0.26)	
p-value [3]		0.204		0.404	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	41	78	
Mean (StdDev)	0.9 (1.08)	0.7 (0.86)	1.7 (1.35)	1.3 (1.27)	
Median	1.0	0.0	2.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C5D1 CFB					
n	21	42	41	76	
LS Mean (StdErr) [2]	-0.45 (0.232)	-0.64 (0.164)	-0.43 (0.195)	-0.90 (0.154)	
95% CI [2]	-0.92, 0.01	-0.97, -0.31	-0.82, -0.04	-1.20, -0.59	
Difference (95% CI) in CFB [2]		-0.18 (-0.67, 0.31)		-0.47 (-0.92, -0.02)	
p-value [3]		0.457		0.042	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	1.1 (1.06)	0.6 (0.82)	1.7 (1.37)	1.2 (1.17)	
Median	1.0	0.0	2.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	-0.32 (0.241)	-0.92 (0.165)	-0.40 (0.206)	-1.13 (0.160)	
95% CI [2]	-0.80, 0.17	-1.25, -0.59	-0.81, 0.01	-1.44, -0.81	
Difference (95% CI) in CFB [2]		-0.60 (-1.11, -0.10)		-0.72 (-1.20, -0.25)	
p-value [3]		0.020		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	1.0 (1.21)	0.8 (0.99)	1.8 (1.38)	1.3 (1.30)	
Median	0.5	0.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	-0.18 (0.259)	-0.58 (0.179)	-0.32 (0.232)	-0.88 (0.183)	
95% CI [2]	-0.70, 0.33	-0.94, -0.22	-0.78, 0.13	-1.24, -0.52	
Difference (95% CI) in CFB [2]		-0.40 (-0.93, 0.14)		-0.55 (-1.08, -0.03)	
Hedges'G (95% CI) in CFB		-0.33 (-0.88, 0.20)		-0.36 (-0.75, 0.03)	
p-value [3]		0.147		0.040	
					0.680

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	2.0 (0.88)	1.7 (1.25)	2.5 (1.07)	2.5 (1.16)	
Median	2.0	2.0	2.0	3.0	
Min, Max	0, 3	0, 4	1, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	1.2 (0.97)	1.2 (1.00)	2.0 (1.13)	1.8 (1.38)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	-0.61 (0.228)	-0.49 (0.156)	-0.44 (0.173)	-0.65 (0.140)	
95% CI [2]	-1.07, -0.15	-0.80, -0.18	-0.78, -0.10	-0.92, -0.37	
Difference (95% CI) in CFB [2]		0.12 (-0.36, 0.60)		-0.21 (-0.61, 0.19)	
p-value [3]		0.627		0.306	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	77	
Mean (StdDev)	1.4 (0.96)	1.0 (1.01)	1.9 (1.18)	1.6 (1.15)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	-0.54 (0.303)	-0.66 (0.199)	-0.49 (0.167)	-0.87 (0.138)	
95% CI [2]	-1.14, 0.07	-1.06, -0.27	-0.82, -0.16	-1.15, -0.60	
Difference (95% CI) in CFB [2]		-0.13 (-0.76, 0.51)		-0.38 (-0.77, 0.01)	
p-value [3]		0.696		0.056	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	80	
Mean (StdDev)	1.4 (1.03)	0.9 (1.06)	1.9 (1.19)	1.7 (1.28)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	19	44	38	79	
LS Mean (StdErr) [2]	-0.55 (0.285)	-0.95 (0.194)	-0.56 (0.199)	-0.84 (0.153)	
95% CI [2]	-1.12, 0.02	-1.34, -0.56	-0.95, -0.17	-1.15, -0.54	
Difference (95% CI) in CFB [2]		-0.40 (-0.99, 0.20)		-0.28 (-0.73, 0.17)	
p-value [3]		0.185		0.213	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	41	78	
Mean (StdDev)	1.2 (1.15)	0.9 (1.03)	1.8 (1.36)	1.6 (1.24)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	21	42	41	76	
LS Mean (StdErr) [2]	-0.60 (0.293)	-0.86 (0.207)	-0.68 (0.203)	-0.95 (0.161)	
95% CI [2]	-1.19, -0.01	-1.27, -0.44	-1.08, -0.28	-1.26, -0.63	
Difference (95% CI) in CFB [2]		-0.26 (-0.87, 0.36)		-0.27 (-0.74, 0.20)	
p-value [3]		0.406		0.266	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	1.4 (1.12)	0.7 (1.03)	1.8 (1.33)	1.6 (1.27)	
Median	2.0	0.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	-0.51 (0.283)	-1.05 (0.194)	-0.59 (0.209)	-0.97 (0.162)	
95% CI [2]	-1.08, 0.06	-1.43, -0.66	-1.01, -0.18	-1.29, -0.65	
Difference (95% CI) in CFB [2]		-0.54 (-1.13, 0.06)		-0.38 (-0.86, 0.11)	
p-value [3]		0.077		0.125	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	1.3 (0.99)	1.0 (1.06)	1.6 (1.34)	1.5 (1.31)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	-0.48 (0.273)	-0.66 (0.188)	-0.76 (0.218)	-0.93 (0.172)	
95% CI [2]	-1.03, 0.06	-1.04, -0.29	-1.19, -0.33	-1.27, -0.59	
Difference (95% CI) in CFB [2]		-0.18 (-0.74, 0.39)		-0.17 (-0.66, 0.33)	
Hedges'G (95% CI) in CFB		-0.14 (-0.68, 0.39)		-0.12 (-0.51, 0.27)	
p-value [3]		0.533		0.502	
					0.964

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	2.3 (1.09)	2.2 (1.11)	2.8 (1.12)	2.9 (1.07)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	2.0 (1.17)	1.9 (1.07)	2.5 (1.05)	2.3 (1.21)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	-0.30 (0.209)	-0.28 (0.143)	-0.31 (0.157)	-0.63 (0.126)	
95% CI [2]	-0.72, 0.11	-0.57, 0.00	-0.62, -0.00	-0.88, -0.38	
Difference (95% CI) in CFB [2]		0.02 (-0.42, 0.46)		-0.32 (-0.68, 0.05)	
p-value [3]		0.929		0.086	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	78	
Mean (StdDev)	2.0 (1.17)	1.6 (1.12)	2.4 (1.13)	2.3 (1.11)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	20	47	44	77	
LS Mean (StdErr) [2]	-0.26 (0.211)	-0.44 (0.138)	-0.45 (0.171)	-0.63 (0.141)	
95% CI [2]	-0.68, 0.16	-0.71, -0.16	-0.78, -0.11	-0.91, -0.35	
Difference (95% CI) in CFB [2]		-0.18 (-0.62, 0.26)		-0.18 (-0.58, 0.22)	
p-value [3]		0.421		0.368	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	2.2 (1.17)	1.6 (1.06)	2.4 (1.12)	2.2 (1.19)	
Median	2.0	1.5	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	-0.02 (0.253)	-0.52 (0.172)	-0.42 (0.202)	-0.74 (0.155)	
95% CI [2]	-0.53, 0.49	-0.86, -0.17	-0.82, -0.02	-1.05, -0.43	
Difference (95% CI) in CFB [2]		-0.50 (-1.03, 0.03)		-0.32 (-0.77, 0.14)	
p-value [3]		0.065		0.172	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	41	78	
Mean (StdDev)	1.9 (1.08)	1.6 (1.03)	2.4 (1.09)	2.2 (1.17)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	21	42	41	76	
LS Mean (StdErr) [2]	-0.40 (0.263)	-0.59 (0.186)	-0.43 (0.201)	-0.80 (0.159)	
95% CI [2]	-0.92, 0.13	-0.96, -0.22	-0.83, -0.03	-1.11, -0.48	
Difference (95% CI) in CFB [2]		-0.20 (-0.75, 0.36)		-0.36 (-0.83, 0.10)	
p-value [3]		0.482		0.124	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	2.3 (1.11)	1.4 (0.94)	2.3 (1.30)	2.0 (1.21)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	0.13 (0.270)	-0.68 (0.185)	-0.55 (0.211)	-0.92 (0.164)	
95% CI [2]	-0.41, 0.67	-1.05, -0.32	-0.96, -0.13	-1.25, -0.60	
Difference (95% CI) in CFB [2]		-0.82 (-1.39, -0.25)		-0.38 (-0.86, 0.11)	
p-value [3]		0.005		0.127	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	2.0 (1.25)	1.5 (0.95)	2.4 (1.21)	2.0 (1.22)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	-0.19 (0.268)	-0.56 (0.185)	-0.34 (0.204)	-0.89 (0.161)	
95% CI [2]	-0.73, 0.34	-0.93, -0.19	-0.75, 0.06	-1.20, -0.57	
Difference (95% CI) in CFB [2]		-0.37 (-0.93, 0.19)		-0.54 (-1.01, -0.08)	
Hedges'G (95% CI) in CFB		-0.30 (-0.85, 0.23)		-0.40 (-0.80, -0.01)	
p-value [3]		0.189		0.023	
					0.636

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	1.8 (1.34)	1.6 (1.28)	2.3 (1.36)	2.3 (1.26)	
Median	2.0	1.0	2.5	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	1.7 (1.14)	1.2 (1.23)	2.0 (1.37)	1.9 (1.30)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	-0.08 (0.226)	-0.38 (0.154)	-0.34 (0.161)	-0.42 (0.130)	
95% CI [2]	-0.54, 0.37	-0.69, -0.07	-0.66, -0.03	-0.68, -0.16	
Difference (95% CI) in CFB [2]		-0.30 (-0.77, 0.18)		-0.08 (-0.45, 0.29)	
p-value [3]		0.216		0.680	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	44	78	
Mean (StdDev)	1.5 (1.19)	1.2 (1.25)	1.8 (1.31)	1.6 (1.21)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	20	47	43	77	
LS Mean (StdErr) [2]	-0.33 (0.198)	-0.34 (0.130)	-0.61 (0.181)	-0.71 (0.148)	
95% CI [2]	-0.73, 0.06	-0.60, -0.08	-0.97, -0.26	-1.01, -0.42	
Difference (95% CI) in CFB [2]		-0.01 (-0.43, 0.41)		-0.10 (-0.52, 0.32)	
p-value [3]		0.972		0.643	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	1.5 (1.21)	1.1 (1.24)	1.8 (1.43)	1.7 (1.30)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	-0.45 (0.234)	-0.56 (0.160)	-0.53 (0.214)	-0.67 (0.164)	
95% CI [2]	-0.92, 0.02	-0.88, -0.24	-0.95, -0.10	-0.99, -0.34	
Difference (95% CI) in CFB [2]		-0.11 (-0.60, 0.38)		-0.14 (-0.63, 0.34)	
p-value [3]		0.649		0.560	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	41	78	
Mean (StdDev)	1.5 (1.20)	0.9 (1.10)	1.8 (1.41)	1.5 (1.28)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	21	42	41	76	
LS Mean (StdErr) [2]	-0.16 (0.230)	-0.67 (0.163)	-0.68 (0.219)	-0.88 (0.173)	
95% CI [2]	-0.62, 0.30	-1.00, -0.35	-1.11, -0.24	-1.22, -0.53	
Difference (95% CI) in CFB [2]		-0.51 (-0.99, -0.02)		-0.20 (-0.71, 0.31)	
p-value [3]		0.040		0.434	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	1.9 (1.25)	1.0 (1.17)	1.8 (1.50)	1.4 (1.23)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	-0.13 (0.268)	-0.70 (0.183)	-0.42 (0.210)	-0.90 (0.163)	
95% CI [2]	-0.67, 0.40	-1.07, -0.34	-0.83, -0.00	-1.23, -0.58	
Difference (95% CI) in CFB [2]		-0.57 (-1.13, -0.00)		-0.49 (-0.97, -0.00)	
p-value [3]		0.048		0.049	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	1.5 (1.37)	0.9 (1.17)	1.9 (1.35)	1.4 (1.35)	
Median	1.0	0.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	-0.39 (0.240)	-0.67 (0.165)	-0.39 (0.203)	-0.79 (0.160)	
95% CI [2]	-0.87, 0.09	-1.00, -0.34	-0.80, 0.01	-1.11, -0.48	
Difference (95% CI) in CFB [2]		-0.28 (-0.78, 0.22)		-0.40 (-0.86, 0.06)	
Hedges'G (95% CI) in CFB		-0.25 (-0.80, 0.28)		-0.29 (-0.69, 0.09)	
p-value [3]		0.270		0.090	
					0.796

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	44	85	
Mean (StdDev)	2.1 (0.99)	2.1 (1.07)	2.5 (1.05)	2.6 (1.12)	
Median	2.0	2.0	2.0	3.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	1.6 (0.99)	1.5 (1.09)	2.0 (1.12)	2.0 (1.15)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	23	48	43	83	
LS Mean (StdErr) [2]	-0.42 (0.204)	-0.60 (0.139)	-0.49 (0.188)	-0.68 (0.152)	
95% CI [2]	-0.83, -0.02	-0.88, -0.33	-0.87, -0.12	-0.98, -0.38	
Difference (95% CI) in CFB [2]		-0.18 (-0.61, 0.25)		-0.19 (-0.62, 0.25)	
p-value [3]		0.401		0.393	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	77	
Mean (StdDev)	1.6 (1.05)	1.4 (0.91)	2.1 (1.14)	1.8 (1.12)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	20	47	44	76	
LS Mean (StdErr) [2]	-0.43 (0.237)	-0.66 (0.155)	-0.45 (0.193)	-0.83 (0.160)	
95% CI [2]	-0.91, 0.04	-0.97, -0.35	-0.83, -0.06	-1.15, -0.52	
Difference (95% CI) in CFB [2]		-0.22 (-0.72, 0.27)		-0.39 (-0.84, 0.07)	
p-value [3]		0.371		0.093	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	1.8 (1.12)	1.3 (1.07)	1.9 (1.13)	1.8 (1.17)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	19	44	38	80	
LS Mean (StdErr) [2]	-0.24 (0.249)	-0.81 (0.170)	-0.61 (0.206)	-0.83 (0.158)	
95% CI [2]	-0.74, 0.26	-1.15, -0.47	-1.02, -0.20	-1.14, -0.52	
Difference (95% CI) in CFB [2]		-0.57 (-1.09, -0.05)		-0.22 (-0.69, 0.24)	
p-value [3]		0.031		0.350	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	41	78	
Mean (StdDev)	1.5 (1.12)	1.1 (1.06)	1.9 (1.20)	1.7 (1.16)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	21	42	41	76	
LS Mean (StdErr) [2]	-0.52 (0.268)	-1.00 (0.189)	-0.69 (0.212)	-0.97 (0.168)	
95% CI [2]	-1.06, 0.01	-1.38, -0.62	-1.11, -0.27	-1.30, -0.64	
Difference (95% CI) in CFB [2]		-0.48 (-1.04, 0.09)		-0.28 (-0.77, 0.21)	
p-value [3]		0.096		0.261	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	1.8 (1.04)	1.2 (1.09)	1.9 (1.25)	1.6 (1.16)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	21	45	39	77	
LS Mean (StdErr) [2]	-0.22 (0.245)	-0.88 (0.167)	-0.66 (0.215)	-1.10 (0.167)	
95% CI [2]	-0.71, 0.27	-1.21, -0.54	-1.09, -0.24	-1.43, -0.77	
Difference (95% CI) in CFB [2]		-0.66 (-1.17, -0.14)		-0.44 (-0.93, 0.06)	
p-value [3]		0.013		0.083	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	1.5 (1.18)	1.2 (1.07)	2.0 (1.32)	1.7 (1.35)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	20	45	40	75	
LS Mean (StdErr) [2]	-0.34 (0.285)	-0.91 (0.197)	-0.51 (0.247)	-0.94 (0.195)	
95% CI [2]	-0.91, 0.23	-1.30, -0.52	-1.00, -0.02	-1.33, -0.56	
Difference (95% CI) in CFB [2]		-0.57 (-1.16, 0.02)		-0.43 (-1.00, 0.13)	
Hedges'G (95% CI) in CFB		-0.43 (-0.99, 0.10)		-0.26 (-0.66, 0.12)	
p-value [3]		0.059		0.131	
					0.757

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	24	49	43	85	
Mean (StdDev)	1.7 (1.08)	1.8 (1.09)	2.2 (1.32)	2.4 (1.19)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	1.6 (1.12)	1.5 (1.20)	2.0 (1.26)	1.9 (1.18)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	23	48	42	83	
LS Mean (StdErr) [2]	-0.18 (0.227)	-0.32 (0.155)	-0.17 (0.178)	-0.52 (0.143)	
95% CI [2]	-0.63, 0.27	-0.63, -0.01	-0.52, 0.18	-0.80, -0.23	
Difference (95% CI) in CFB [2]		-0.14 (-0.61, 0.34)		-0.35 (-0.76, 0.06)	
p-value [3]		0.562		0.097	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	78	
Mean (StdDev)	1.6 (1.09)	1.2 (1.05)	1.8 (1.24)	1.8 (1.10)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	20	47	43	77	
LS Mean (StdErr) [2]	0.04 (0.201)	-0.55 (0.132)	-0.33 (0.176)	-0.64 (0.144)	
95% CI [2]	-0.36, 0.44	-0.81, -0.29	-0.68, 0.02	-0.92, -0.35	
Difference (95% CI) in CFB [2]		-0.59 (-1.01, -0.17)		-0.31 (-0.72, 0.10)	
p-value [3]		0.007		0.141	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	1.5 (1.17)	1.2 (1.17)	1.8 (1.27)	1.8 (1.26)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	19	44	37	80	
LS Mean (StdErr) [2]	-0.02 (0.239)	-0.61 (0.163)	-0.35 (0.213)	-0.71 (0.162)	
95% CI [2]	-0.49, 0.46	-0.93, -0.28	-0.77, 0.07	-1.03, -0.39	
Difference (95% CI) in CFB [2]		-0.59 (-1.09, -0.09)		-0.36 (-0.84, 0.12)	
p-value [3]		0.021		0.145	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	41	78	
Mean (StdDev)	1.3 (0.93)	1.2 (1.06)	1.8 (1.17)	1.6 (1.16)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	21	42	40	76	
LS Mean (StdErr) [2]	-0.01 (0.207)	-0.58 (0.146)	-0.45 (0.212)	-0.80 (0.166)	
95% CI [2]	-0.42, 0.41	-0.87, -0.29	-0.86, -0.03	-1.13, -0.47	
Difference (95% CI) in CFB [2]		-0.57 (-1.01, -0.14)		-0.35 (-0.84, 0.14)	
p-value [3]		0.011		0.157	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	1.7 (1.01)	1.0 (0.99)	1.7 (1.32)	1.6 (1.25)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	21	45	38	77	
LS Mean (StdErr) [2]	0.09 (0.212)	-0.87 (0.145)	-0.43 (0.218)	-0.84 (0.168)	
95% CI [2]	-0.33, 0.51	-1.16, -0.58	-0.87, -0.00	-1.17, -0.51	
Difference (95% CI) in CFB [2]		-0.96 (-1.40, -0.51)		-0.41 (-0.91, 0.10)	
p-value [3]		<0.0001		0.112	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.5a
Change from Baseline in MC-QoL Individual Item Scores by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	1.4 (1.10)	1.2 (1.09)	1.8 (1.20)	1.7 (1.32)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	20	45	39	75	
LS Mean (StdErr) [2]	0.01 (0.236)	-0.57 (0.163)	-0.27 (0.229)	-0.65 (0.179)	
95% CI [2]	-0.46, 0.48	-0.90, -0.25	-0.72, 0.18	-1.00, -0.29	
Difference (95% CI) in CFB [2]		-0.58 (-1.07, -0.09)		-0.38 (-0.90, 0.15)	
Hedges'G (95% CI) in CFB		-0.53 (-1.09, -0.00)		-0.25 (-0.64, 0.14)	
p-value [3]		0.021		0.156	
					0.570

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ism-a.sas Date: 16:02/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	2.7 (0.75)	2.4 (0.75)	2.7 (1.24)	2.3 (1.20)	
Median	3.0	2.0	3.0	2.0	
Min, Max	2, 4	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	2.0 (0.85)	1.8 (1.05)	2.3 (1.10)	1.6 (0.92)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	-0.55 (0.375)	-0.56 (0.245)	-0.36 (0.138)	-0.64 (0.100)	
95% CI [2]	-1.31, 0.21	-1.06, -0.07	-0.63, -0.08	-0.84, -0.44	
Difference (95% CI) in CFB [2]		-0.01 (-0.90, 0.87)		-0.28 (-0.61, 0.05)	
p-value [3]		0.974		0.095	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	102	
Mean (StdDev)	1.7 (0.72)	1.9 (0.95)	2.2 (1.21)	1.4 (0.95)	
Median	2.0	2.0	2.0	1.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	-0.89 (0.317)	-0.53 (0.207)	-0.54 (0.165)	-0.77 (0.120)	
95% CI [2]	-1.53, -0.25	-0.95, -0.11	-0.87, -0.21	-1.01, -0.54	
Difference (95% CI) in CFB [2]		0.36 (-0.39, 1.11)		-0.23 (-0.63, 0.16)	
p-value [3]		0.337		0.249	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	1.8 (0.83)	1.6 (1.18)	2.3 (1.14)	1.4 (0.98)	
Median	2.0	1.0	2.0	1.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	-0.80 (0.355)	-0.90 (0.229)	-0.39 (0.180)	-0.88 (0.125)	
95% CI [2]	-1.52, -0.08	-1.37, -0.44	-0.75, -0.04	-1.13, -0.63	
Difference (95% CI) in CFB [2]		-0.10 (-0.93, 0.73)		-0.49 (-0.91, -0.06)	
p-value [3]		0.801		0.024	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	98	
Mean (StdDev)	1.6 (0.74)	1.5 (1.03)	2.4 (1.24)	1.3 (0.98)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C5D1 CFB					
n	12	25	50	93	
LS Mean (StdErr) [2]	-1.06 (0.353)	-0.87 (0.232)	-0.22 (0.175)	-0.85 (0.131)	
95% CI [2]	-1.78, -0.35	-1.34, -0.39	-0.56, 0.13	-1.11, -0.59	
Difference (95% CI) in CFB [2]		0.20 (-0.62, 1.02)		-0.63 (-1.06, -0.21)	
p-value [3]		0.628		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	1.6 (0.84)	1.6 (1.08)	2.3 (1.28)	1.4 (1.05)	
Median	2.0	2.0	3.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-0.90 (0.397)	-0.70 (0.254)	-0.42 (0.170)	-0.78 (0.122)	
95% CI [2]	-1.71, -0.10	-1.21, -0.18	-0.75, -0.08	-1.02, -0.54	
Difference (95% CI) in CFB [2]		0.20 (-0.72, 1.13)		-0.37 (-0.78, 0.04)	
p-value [3]		0.655		0.079	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	2.0 (1.00)	1.5 (1.05)	2.3 (1.21)	1.3 (0.99)	
Median	2.0	1.0	3.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	-0.63 (0.367)	-0.87 (0.237)	-0.33 (0.159)	-0.82 (0.114)	
95% CI [2]	-1.38, 0.12	-1.36, -0.39	-0.65, -0.02	-1.04, -0.59	
Difference (95% CI) in CFB [2]		-0.24 (-1.10, 0.61)		-0.48 (-0.87, -0.10)	
Hedges'G (95% CI) in CFB		-0.20 (-0.96, 0.53)		-0.43 (-0.79, -0.09)	
p-value [3]		0.568		0.013	
					0.814

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	2.3 (0.95)	2.1 (1.09)	2.5 (1.22)	2.0 (1.16)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	1.8 (1.21)	1.5 (1.01)	2.2 (1.14)	1.4 (0.97)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	-0.07 (0.387)	-0.54 (0.253)	-0.26 (0.150)	-0.57 (0.109)	
95% CI [2]	-0.85, 0.72	-1.05, -0.03	-0.55, 0.04	-0.79, -0.36	
Difference (95% CI) in CFB [2]		-0.47 (-1.39, 0.44)		-0.32 (-0.68, 0.04)	
p-value [3]		0.301		0.085	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	102	
Mean (StdDev)	1.7 (0.96)	1.5 (0.95)	2.2 (1.29)	1.4 (1.01)	
Median	2.0	1.5	2.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	-0.40 (0.342)	-0.62 (0.223)	-0.30 (0.174)	-0.58 (0.127)	
95% CI [2]	-1.09, 0.30	-1.08, -0.17	-0.64, 0.05	-0.83, -0.33	
Difference (95% CI) in CFB [2]		-0.22 (-1.03, 0.58)		-0.28 (-0.70, 0.14)	
p-value [3]		0.575		0.184	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	1.8 (1.09)	1.6 (1.06)	2.2 (1.12)	1.2 (0.99)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	-0.23 (0.401)	-0.53 (0.259)	-0.24 (0.168)	-0.80 (0.117)	
95% CI [2]	-1.05, 0.58	-1.06, -0.00	-0.57, 0.10	-1.03, -0.57	
Difference (95% CI) in CFB [2]		-0.30 (-1.24, 0.64)		-0.56 (-0.96, -0.16)	
p-value [3]		0.520		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	98	
Mean (StdDev)	1.6 (0.93)	1.5 (0.86)	2.1 (1.36)	1.3 (1.03)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C5D1 CFB					
n	12	25	50	93	
LS Mean (StdErr) [2]	-0.33 (0.343)	-0.52 (0.226)	-0.28 (0.177)	-0.67 (0.134)	
95% CI [2]	-1.03, 0.36	-0.98, -0.07	-0.64, 0.07	-0.93, -0.40	
Difference (95% CI) in CFB [2]		-0.19 (-0.99, 0.60)		-0.38 (-0.82, 0.05)	
p-value [3]		0.627		0.080	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	1.9 (0.95)	1.6 (1.05)	2.1 (1.25)	1.4 (1.08)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-0.14 (0.381)	-0.46 (0.244)	-0.25 (0.173)	-0.71 (0.125)	
95% CI [2]	-0.92, 0.63	-0.96, 0.03	-0.59, 0.10	-0.96, -0.47	
Difference (95% CI) in CFB [2]		-0.32 (-1.20, 0.56)		-0.47 (-0.88, -0.05)	
p-value [3]		0.468		0.029	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	1.8 (1.01)	1.6 (1.08)	2.1 (1.27)	1.3 (1.10)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	-0.23 (0.397)	-0.48 (0.256)	-0.20 (0.176)	-0.63 (0.127)	
95% CI [2]	-1.03, 0.58	-1.00, 0.04	-0.55, 0.14	-0.88, -0.38	
Difference (95% CI) in CFB [2]		-0.26 (-1.18, 0.67)		-0.43 (-0.85, -0.00)	
Hedges'G (95% CI) in CFB		-0.20 (-0.95, 0.53)		-0.34 (-0.69, 0.00)	
p-value [3]		0.579		0.048	
					0.844

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	2.2 (1.01)	2.5 (1.01)	2.3 (1.16)	2.3 (1.11)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	2.3 (1.03)	2.0 (1.22)	2.0 (1.09)	1.8 (1.02)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	0.16 (0.343)	-0.50 (0.224)	-0.31 (0.131)	-0.37 (0.095)	
95% CI [2]	-0.53, 0.86	-0.95, -0.04	-0.57, -0.05	-0.56, -0.19	
Difference (95% CI) in CFB [2]		-0.66 (-1.47, 0.15)		-0.06 (-0.38, 0.26)	
p-value [3]		0.107		0.704	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	102	
Mean (StdDev)	2.0 (1.07)	2.0 (1.15)	2.0 (0.99)	1.7 (1.09)	
Median	2.0	2.5	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	-0.15 (0.351)	-0.48 (0.229)	-0.22 (0.158)	-0.46 (0.115)	
95% CI [2]	-0.86, 0.57	-0.95, -0.02	-0.53, 0.09	-0.69, -0.24	
Difference (95% CI) in CFB [2]		-0.33 (-1.16, 0.49)		-0.25 (-0.63, 0.13)	
p-value [3]		0.418		0.201	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	2.2 (0.99)	1.9 (1.19)	2.0 (1.16)	1.6 (0.98)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	-0.07 (0.347)	-0.58 (0.224)	-0.24 (0.170)	-0.59 (0.118)	
95% CI [2]	-0.78, 0.63	-1.03, -0.12	-0.58, 0.10	-0.82, -0.36	
Difference (95% CI) in CFB [2]		-0.50 (-1.31, 0.31)		-0.35 (-0.75, 0.05)	
p-value [3]		0.214		0.087	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	98	
Mean (StdDev)	1.9 (1.10)	1.7 (1.19)	2.0 (1.28)	1.7 (1.01)	
Median	1.5	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	12	25	50	93	
LS Mean (StdErr) [2]	-0.13 (0.412)	-0.70 (0.271)	-0.23 (0.166)	-0.41 (0.125)	
95% CI [2]	-0.97, 0.71	-1.26, -0.15	-0.55, 0.10	-0.66, -0.16	
Difference (95% CI) in CFB [2]		-0.57 (-1.53, 0.38)		-0.18 (-0.59, 0.22)	
p-value [3]		0.230		0.368	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	1.9 (1.00)	1.9 (1.20)	1.9 (1.21)	1.6 (1.08)	
Median	2.0	2.0	2.0	1.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-0.20 (0.365)	-0.59 (0.234)	-0.33 (0.169)	-0.60 (0.121)	
95% CI [2]	-0.95, 0.54	-1.07, -0.11	-0.66, 0.01	-0.84, -0.36	
Difference (95% CI) in CFB [2]		-0.39 (-1.23, 0.46)		-0.28 (-0.68, 0.13)	
p-value [3]		0.363		0.178	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	2.1 (1.12)	1.8 (1.19)	1.8 (1.14)	1.6 (1.07)	
Median	2.0	2.0	2.0	1.5	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	0.20 (0.460)	-0.71 (0.297)	-0.40 (0.172)	-0.57 (0.124)	
95% CI [2]	-0.73, 1.14	-1.31, -0.10	-0.74, -0.06	-0.81, -0.32	
Difference (95% CI) in CFB [2]		-0.91 (-1.98, 0.16)		-0.17 (-0.58, 0.25)	
Hedges'G (95% CI) in CFB		-0.60 (-1.40, 0.11)		-0.14 (-0.49, 0.21)	
p-value [3]		0.094		0.422	
					0.137

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	2.4 (1.04)	2.0 (1.32)	2.0 (1.25)	2.2 (1.20)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	26	54	110	
Mean (StdDev)	1.7 (1.28)	1.7 (1.19)	1.7 (1.17)	1.4 (1.08)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	25	53	106	
LS Mean (StdErr) [2]	-0.54 (0.431)	-0.28 (0.288)	-0.34 (0.146)	-0.75 (0.106)	
95% CI [2]	-1.42, 0.33	-0.87, 0.30	-0.63, -0.06	-0.96, -0.54	
Difference (95% CI) in CFB [2]		0.26 (-0.75, 1.28)		-0.41 (-0.76, -0.06)	
p-value [3]		0.603		0.023	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	102	
Mean (StdDev)	1.5 (1.30)	1.7 (1.38)	1.8 (1.30)	1.4 (1.06)	
Median	1.0	1.0	1.5	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	-0.63 (0.397)	-0.26 (0.259)	-0.21 (0.171)	-0.77 (0.125)	
95% CI [2]	-1.44, 0.17	-0.78, 0.27	-0.54, 0.13	-1.02, -0.52	
Difference (95% CI) in CFB [2]		0.38 (-0.56, 1.31)		-0.56 (-0.97, -0.15)	
p-value [3]		0.418		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	1.8 (1.14)	1.6 (1.18)	1.7 (1.25)	1.4 (1.18)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	-0.71 (0.369)	-0.36 (0.238)	-0.38 (0.174)	-0.81 (0.121)	
95% CI [2]	-1.46, 0.04	-0.85, 0.12	-0.73, -0.04	-1.05, -0.57	
Difference (95% CI) in CFB [2]		0.35 (-0.51, 1.21)		-0.42 (-0.83, -0.01)	
p-value [3]		0.415		0.044	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	98	
Mean (StdDev)	1.7 (0.99)	1.5 (1.17)	1.8 (1.14)	1.3 (1.15)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	12	25	50	93	
LS Mean (StdErr) [2]	-0.66 (0.373)	-0.32 (0.246)	-0.16 (0.174)	-0.92 (0.131)	
95% CI [2]	-1.41, 0.10	-0.82, 0.18	-0.50, 0.18	-1.18, -0.66	
Difference (95% CI) in CFB [2]		0.34 (-0.52, 1.21)		-0.76 (-1.18, -0.34)	
p-value [3]		0.429		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	1.7 (1.27)	1.6 (1.19)	1.7 (1.18)	1.2 (1.09)	
Median	1.5	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-0.62 (0.396)	-0.32 (0.254)	-0.23 (0.171)	-0.88 (0.123)	
95% CI [2]	-1.42, 0.19	-0.84, 0.20	-0.57, 0.11	-1.12, -0.63	
Difference (95% CI) in CFB [2]		0.30 (-0.62, 1.22)		-0.64 (-1.06, -0.23)	
p-value [3]		0.518		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	1.8 (1.14)	1.6 (1.32)	1.7 (1.09)	1.4 (1.18)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	-0.38 (0.452)	-0.22 (0.293)	-0.26 (0.165)	-0.79 (0.119)	
95% CI [2]	-1.30, 0.54	-0.81, 0.38	-0.58, 0.07	-1.02, -0.55	
Difference (95% CI) in CFB [2]		0.17 (-0.89, 1.22)		-0.53 (-0.93, -0.13)	
Hedges'G (95% CI) in CFB		0.11 (-0.62, 0.86)		-0.45 (-0.81, -0.11)	
p-value [3]		0.751		0.009	
					0.213

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	3.2 (0.69)	3.3 (0.91)	3.1 (0.95)	3.1 (0.93)	
Median	3.0	4.0	3.0	3.0	
Min, Max	2, 4	1, 4	1, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	2.9 (0.96)	2.7 (1.17)	2.8 (0.95)	2.6 (1.06)	
Median	3.0	3.0	3.0	3.0	
Min, Max	2, 4	0, 4	1, 4	0, 4	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	0.02 (0.294)	-0.58 (0.192)	-0.40 (0.129)	-0.49 (0.094)	
95% CI [2]	-0.57, 0.62	-0.97, -0.19	-0.66, -0.15	-0.68, -0.31	
Difference (95% CI) in CFB [2]		-0.60 (-1.29, 0.09)		-0.09 (-0.40, 0.22)	
p-value [3]		0.089		0.561	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	102	
Mean (StdDev)	2.7 (1.29)	2.7 (1.16)	2.7 (1.03)	2.4 (1.07)	
Median	3.0	3.0	3.0	2.0	
Min, Max	0, 4	1, 4	0, 4	0, 4	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	-0.43 (0.362)	-0.61 (0.236)	-0.51 (0.149)	-0.76 (0.108)	
95% CI [2]	-1.17, 0.30	-1.09, -0.13	-0.80, -0.21	-0.98, -0.55	
Difference (95% CI) in CFB [2]		-0.18 (-1.03, 0.68)		-0.26 (-0.61, 0.10)	
p-value [3]		0.677		0.160	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	2.8 (1.30)	2.5 (1.10)	2.7 (1.07)	2.4 (1.13)	
Median	3.0	2.5	3.0	2.0	
Min, Max	1, 4	1, 4	1, 4	0, 4	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	-0.13 (0.367)	-0.69 (0.237)	-0.52 (0.166)	-0.68 (0.115)	
95% CI [2]	-0.88, 0.62	-1.18, -0.21	-0.84, -0.19	-0.91, -0.45	
Difference (95% CI) in CFB [2]		-0.56 (-1.42, 0.29)		-0.16 (-0.55, 0.23)	
p-value [3]		0.189		0.413	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	98	
Mean (StdDev)	2.8 (1.05)	2.6 (1.14)	2.7 (1.24)	2.3 (1.13)	
Median	3.0	3.0	3.0	2.0	
Min, Max	1, 4	1, 4	0, 4	0, 4	
C5D1 CFB					
n	12	25	50	93	
LS Mean (StdErr) [2]	-0.34 (0.327)	-0.73 (0.216)	-0.53 (0.167)	-0.82 (0.126)	
95% CI [2]	-1.01, 0.32	-1.17, -0.29	-0.86, -0.19	-1.07, -0.57	
Difference (95% CI) in CFB [2]		-0.39 (-1.15, 0.37)		-0.29 (-0.70, 0.11)	
p-value [3]		0.309		0.157	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	2.2 (1.05)	2.4 (1.31)	2.7 (1.09)	2.2 (1.12)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-0.89 (0.356)	-0.87 (0.229)	-0.49 (0.169)	-0.78 (0.122)	
95% CI [2]	-1.61, -0.16	-1.34, -0.41	-0.83, -0.16	-1.02, -0.53	
Difference (95% CI) in CFB [2]		0.01 (-0.81, 0.84)		-0.28 (-0.69, 0.12)	
p-value [3]		0.975		0.170	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	2.2 (1.01)	2.6 (1.15)	2.7 (1.09)	2.3 (1.04)	
Median	2.0	3.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	-0.70 (0.371)	-0.62 (0.240)	-0.53 (0.162)	-0.78 (0.117)	
95% CI [2]	-1.46, 0.05	-1.11, -0.13	-0.85, -0.21	-1.02, -0.55	
Difference (95% CI) in CFB [2]		0.08 (-0.78, 0.95)		-0.25 (-0.64, 0.14)	
Hedges'G (95% CI) in CFB		0.07 (-0.67, 0.81)		-0.22 (-0.57, 0.13)	
p-value [3]		0.849		0.203	
					0.419

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	2.5 (1.13)	2.0 (0.94)	2.0 (1.10)	2.1 (1.18)	
Median	3.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	2.2 (0.94)	1.9 (1.03)	1.9 (1.11)	1.8 (1.03)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	-0.32 (0.271)	-0.19 (0.177)	-0.14 (0.132)	-0.34 (0.096)	
95% CI [2]	-0.87, 0.23	-0.55, 0.16	-0.40, 0.12	-0.53, -0.15	
Difference (95% CI) in CFB [2]		0.12 (-0.52, 0.76)		-0.20 (-0.51, 0.12)	
p-value [3]		0.696		0.220	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	102	
Mean (StdDev)	1.9 (1.16)	1.7 (0.93)	1.8 (1.08)	1.6 (1.02)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	-0.70 (0.305)	-0.36 (0.199)	-0.16 (0.155)	-0.54 (0.113)	
95% CI [2]	-1.32, -0.08	-0.77, 0.04	-0.47, 0.14	-0.76, -0.32	
Difference (95% CI) in CFB [2]		0.33 (-0.39, 1.06)		-0.38 (-0.75, -0.00)	
p-value [3]		0.352		0.048	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	2.3 (1.18)	1.7 (1.08)	1.8 (1.18)	1.7 (1.16)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	-0.17 (0.361)	-0.36 (0.233)	-0.34 (0.165)	-0.45 (0.114)	
95% CI [2]	-0.91, 0.56	-0.84, 0.11	-0.66, -0.01	-0.67, -0.22	
Difference (95% CI) in CFB [2]		-0.19 (-1.04, 0.65)		-0.11 (-0.50, 0.28)	
p-value [3]		0.642		0.576	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	98	
Mean (StdDev)	2.1 (1.29)	1.7 (1.13)	1.8 (1.23)	1.7 (1.15)	
Median	2.5	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	12	25	50	93	
LS Mean (StdErr) [2]	-0.43 (0.350)	-0.33 (0.230)	-0.24 (0.150)	-0.39 (0.113)	
95% CI [2]	-1.14, 0.28	-0.79, 0.14	-0.53, 0.06	-0.61, -0.16	
Difference (95% CI) in CFB [2]		0.10 (-0.71, 0.92)		-0.15 (-0.51, 0.21)	
p-value [3]		0.796		0.417	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	1.9 (1.14)	1.8 (1.27)	1.8 (1.08)	1.5 (1.09)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-0.75 (0.312)	-0.25 (0.200)	-0.27 (0.151)	-0.57 (0.109)	
95% CI [2]	-1.38, -0.12	-0.66, 0.16	-0.57, 0.03	-0.78, -0.35	
Difference (95% CI) in CFB [2]		0.50 (-0.23, 1.23)		-0.30 (-0.66, 0.07)	
p-value [3]		0.171		0.109	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	1.8 (1.07)	1.6 (1.11)	1.7 (1.11)	1.5 (1.11)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	-0.53 (0.320)	-0.24 (0.207)	-0.35 (0.161)	-0.50 (0.116)	
95% CI [2]	-1.18, 0.12	-0.67, 0.18	-0.67, -0.03	-0.73, -0.27	
Difference (95% CI) in CFB [2]		0.29 (-0.46, 1.03)		-0.15 (-0.54, 0.23)	
Hedges'G (95% CI) in CFB		0.27 (-0.45, 1.04)		-0.14 (-0.48, 0.21)	
p-value [3]		0.440		0.431	
					0.339

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	2.5 (1.27)	2.6 (1.31)	2.7 (1.13)	2.7 (1.20)	
Median	3.0	3.0	3.0	3.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	26	54	110	
Mean (StdDev)	1.9 (1.13)	2.2 (1.42)	2.4 (1.04)	2.1 (1.07)	
Median	2.0	2.5	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	25	53	106	
LS Mean (StdErr) [2]	-0.48 (0.318)	-0.18 (0.213)	-0.31 (0.125)	-0.54 (0.091)	
95% CI [2]	-1.12, 0.17	-0.61, 0.25	-0.55, -0.06	-0.72, -0.37	
Difference (95% CI) in CFB [2]		0.30 (-0.45, 1.05)		-0.24 (-0.54, 0.06)	
p-value [3]		0.424		0.118	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	102	
Mean (StdDev)	2.0 (1.31)	2.0 (1.40)	2.3 (1.06)	2.0 (1.19)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	-0.59 (0.369)	-0.57 (0.241)	-0.52 (0.156)	-0.63 (0.113)	
95% CI [2]	-1.34, 0.16	-1.06, -0.08	-0.83, -0.21	-0.85, -0.41	
Difference (95% CI) in CFB [2]		0.02 (-0.85, 0.89)		-0.11 (-0.49, 0.26)	
p-value [3]		0.965		0.553	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	2.2 (1.01)	2.3 (1.42)	2.4 (1.16)	2.1 (1.17)	
Median	2.0	2.5	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	-0.42 (0.415)	-0.53 (0.268)	-0.31 (0.171)	-0.58 (0.119)	
95% CI [2]	-1.27, 0.43	-1.07, 0.02	-0.65, 0.03	-0.81, -0.35	
Difference (95% CI) in CFB [2]		-0.11 (-1.08, 0.86)		-0.27 (-0.67, 0.14)	
p-value [3]		0.822		0.195	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	98	
Mean (StdDev)	2.6 (0.94)	2.1 (1.35)	2.4 (1.16)	2.1 (1.19)	
Median	3.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	12	25	50	93	
LS Mean (StdErr) [2]	-0.07 (0.345)	-0.56 (0.227)	-0.38 (0.156)	-0.59 (0.118)	
95% CI [2]	-0.77, 0.63	-1.02, -0.09	-0.69, -0.07	-0.82, -0.36	
Difference (95% CI) in CFB [2]		-0.48 (-1.28, 0.32)		-0.21 (-0.59, 0.17)	
p-value [3]		0.229		0.270	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	2.4 (1.08)	2.1 (1.40)	2.5 (1.22)	2.0 (1.16)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-0.13 (0.357)	-0.50 (0.229)	-0.32 (0.169)	-0.64 (0.122)	
95% CI [2]	-0.85, 0.60	-0.96, -0.03	-0.65, 0.02	-0.88, -0.40	
Difference (95% CI) in CFB [2]		-0.37 (-1.20, 0.46)		-0.32 (-0.73, 0.09)	
p-value [3]		0.373		0.120	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	1.8 (1.07)	2.2 (1.40)	2.3 (1.18)	2.1 (1.14)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	-0.28 (0.321)	-0.28 (0.208)	-0.40 (0.160)	-0.54 (0.115)	
95% CI [2]	-0.94, 0.37	-0.70, 0.14	-0.71, -0.08	-0.76, -0.31	
Difference (95% CI) in CFB [2]		0.01 (-0.74, 0.76)		-0.14 (-0.52, 0.24)	
Hedges'G (95% CI) in CFB		0.01 (-0.73, 0.75)		-0.12 (-0.47, 0.22)	
p-value [3]		0.987		0.475	
					0.592

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	2.4 (1.33)	2.7 (1.17)	2.2 (1.10)	2.6 (1.09)	
Median	2.0	3.0	2.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	53	110	
Mean (StdDev)	2.2 (1.15)	2.1 (1.34)	2.0 (1.21)	2.0 (1.08)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	26	52	106	
LS Mean (StdErr) [2]	0.16 (0.293)	-0.47 (0.191)	-0.14 (0.122)	-0.53 (0.088)	
95% CI [2]	-0.44, 0.75	-0.86, -0.08	-0.38, 0.10	-0.70, -0.36	
Difference (95% CI) in CFB [2]		-0.63 (-1.32, 0.06)		-0.39 (-0.68, -0.10)	
p-value [3]		0.074		0.009	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	102	
Mean (StdDev)	2.3 (1.23)	2.2 (1.29)	2.0 (1.20)	1.8 (1.08)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	0.26 (0.258)	-0.48 (0.169)	-0.30 (0.124)	-0.78 (0.091)	
95% CI [2]	-0.27, 0.78	-0.82, -0.14	-0.54, -0.05	-0.96, -0.60	
Difference (95% CI) in CFB [2]		-0.74 (-1.35, -0.13)		-0.48 (-0.78, -0.18)	
p-value [3]		0.019		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	2.0 (1.15)	2.3 (1.37)	2.0 (1.22)	1.8 (1.09)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	0.13 (0.321)	-0.33 (0.207)	-0.35 (0.142)	-0.78 (0.099)	
95% CI [2]	-0.53, 0.78	-0.75, 0.09	-0.63, -0.07	-0.97, -0.58	
Difference (95% CI) in CFB [2]		-0.46 (-1.21, 0.29)		-0.42 (-0.76, -0.09)	
p-value [3]		0.223		0.014	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	98	
Mean (StdDev)	2.2 (1.05)	2.2 (1.35)	2.0 (1.29)	1.8 (1.07)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	12	25	50	93	
LS Mean (StdErr) [2]	0.10 (0.327)	-0.41 (0.216)	-0.26 (0.144)	-0.78 (0.108)	
95% CI [2]	-0.56, 0.77	-0.84, 0.03	-0.54, 0.03	-0.99, -0.56	
Difference (95% CI) in CFB [2]		-0.51 (-1.27, 0.25)		-0.52 (-0.87, -0.17)	
p-value [3]		0.182		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	1.9 (1.07)	2.0 (1.37)	1.9 (1.28)	1.7 (1.17)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-0.18 (0.336)	-0.64 (0.216)	-0.32 (0.151)	-0.82 (0.109)	
95% CI [2]	-0.86, 0.50	-1.08, -0.20	-0.62, -0.02	-1.03, -0.60	
Difference (95% CI) in CFB [2]		-0.46 (-1.24, 0.32)		-0.50 (-0.86, -0.13)	
p-value [3]		0.241		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	1.8 (1.14)	2.1 (1.32)	2.0 (1.22)	1.7 (1.17)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	0.11 (0.335)	-0.59 (0.217)	-0.22 (0.146)	-0.85 (0.105)	
95% CI [2]	-0.57, 0.80	-1.03, -0.15	-0.51, 0.07	-1.06, -0.64	
Difference (95% CI) in CFB [2]		-0.71 (-1.49, 0.08)		-0.63 (-0.98, -0.28)	
Hedges'G (95% CI) in CFB		-0.64 (-1.44, 0.07)		-0.61 (-0.97, -0.26)	
p-value [3]		0.076		<0.001	
					0.876

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	2.3 (1.38)	2.1 (1.41)	1.9 (1.39)	2.0 (1.43)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	2.0 (1.20)	1.7 (1.23)	1.6 (1.42)	1.5 (1.38)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	0.23 (0.378)	-0.34 (0.247)	-0.39 (0.190)	-0.52 (0.138)	
95% CI [2]	-0.53, 1.00	-0.84, 0.16	-0.77, -0.01	-0.80, -0.25	
Difference (95% CI) in CFB [2]		-0.57 (-1.46, 0.32)		-0.13 (-0.59, 0.32)	
p-value [3]		0.204		0.568	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	101	
Mean (StdDev)	2.3 (1.23)	1.6 (1.39)	1.5 (1.31)	1.5 (1.32)	
Median	2.0	1.5	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	0.65 (0.370)	-0.45 (0.242)	-0.39 (0.200)	-0.55 (0.146)	
95% CI [2]	-0.11, 1.40	-0.94, 0.04	-0.79, 0.00	-0.84, -0.26	
Difference (95% CI) in CFB [2]		-1.10 (-1.97, -0.22)		-0.16 (-0.64, 0.32)	
p-value [3]		0.015		0.522	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	1.8 (1.28)	1.7 (1.27)	1.8 (1.24)	1.4 (1.29)	
Median	2.0	1.5	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	0.24 (0.432)	-0.38 (0.279)	-0.15 (0.212)	-0.60 (0.147)	
95% CI [2]	-0.64, 1.12	-0.95, 0.19	-0.57, 0.26	-0.89, -0.31	
Difference (95% CI) in CFB [2]		-0.62 (-1.63, 0.38)		-0.45 (-0.95, 0.05)	
p-value [3]		0.216		0.079	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	49	99	
Mean (StdDev)	1.8 (1.25)	1.6 (1.33)	1.8 (1.23)	1.3 (1.26)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	12	25	49	94	
LS Mean (StdErr) [2]	-0.12 (0.346)	-0.44 (0.228)	-0.12 (0.207)	-0.85 (0.153)	
95% CI [2]	-0.83, 0.58	-0.91, 0.02	-0.53, 0.28	-1.15, -0.55	
Difference (95% CI) in CFB [2]		-0.32 (-1.12, 0.49)		-0.73 (-1.23, -0.23)	
p-value [3]		0.426		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	1.7 (1.33)	1.6 (1.22)	1.9 (1.31)	1.3 (1.31)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-0.21 (0.348)	-0.48 (0.223)	-0.07 (0.208)	-0.63 (0.149)	
95% CI [2]	-0.92, 0.50	-0.93, -0.02	-0.48, 0.34	-0.93, -0.34	
Difference (95% CI) in CFB [2]		-0.27 (-1.07, 0.54)		-0.56 (-1.06, -0.07)	
p-value [3]		0.510		0.027	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	1.8 (1.14)	1.6 (1.38)	1.6 (1.35)	1.3 (1.25)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	0.14 (0.336)	-0.42 (0.217)	-0.36 (0.204)	-0.74 (0.147)	
95% CI [2]	-0.55, 0.82	-0.86, 0.02	-0.76, 0.04	-1.03, -0.45	
Difference (95% CI) in CFB [2]		-0.55 (-1.34, 0.23)		-0.38 (-0.87, 0.11)	
Hedges'G (95% CI) in CFB		-0.50 (-1.29, 0.22)		-0.26 (-0.62, 0.08)	
p-value [3]		0.161		0.123	
					0.975

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	2.8 (0.83)	2.4 (1.36)	2.5 (1.33)	2.7 (1.27)	
Median	3.0	3.0	3.0	3.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	2.5 (0.99)	2.0 (1.22)	2.2 (1.28)	2.0 (1.34)	
Median	3.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	0.03 (0.287)	-0.36 (0.188)	-0.33 (0.163)	-0.66 (0.119)	
95% CI [2]	-0.56, 0.61	-0.74, 0.02	-0.66, -0.01	-0.89, -0.42	
Difference (95% CI) in CFB [2]		-0.39 (-1.07, 0.29)		-0.32 (-0.72, 0.07)	
p-value [3]		0.254		0.106	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	101	
Mean (StdDev)	2.3 (1.11)	1.9 (1.34)	2.3 (1.25)	1.8 (1.30)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	-0.11 (0.306)	-0.50 (0.200)	-0.30 (0.171)	-0.85 (0.125)	
95% CI [2]	-0.73, 0.51	-0.90, -0.09	-0.64, 0.04	-1.09, -0.60	
Difference (95% CI) in CFB [2]		-0.38 (-1.10, 0.34)		-0.55 (-0.96, -0.14)	
p-value [3]		0.289		0.009	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	2.0 (1.15)	2.3 (1.57)	2.1 (1.37)	1.9 (1.29)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	-0.29 (0.456)	-0.30 (0.295)	-0.48 (0.178)	-0.87 (0.123)	
95% CI [2]	-1.22, 0.64	-0.90, 0.30	-0.83, -0.13	-1.12, -0.63	
Difference (95% CI) in CFB [2]		-0.02 (-1.08, 1.05)		-0.40 (-0.82, 0.02)	
p-value [3]		0.976		0.064	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	49	99	
Mean (StdDev)	2.0 (1.11)	1.8 (1.29)	2.2 (1.25)	1.6 (1.23)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	12	25	49	94	
LS Mean (StdErr) [2]	-0.55 (0.356)	-0.43 (0.235)	-0.34 (0.178)	-1.13 (0.132)	
95% CI [2]	-1.27, 0.18	-0.91, 0.05	-0.70, 0.01	-1.39, -0.86	
Difference (95% CI) in CFB [2]		0.12 (-0.71, 0.95)		-0.78 (-1.21, -0.35)	
p-value [3]		0.775		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	2.2 (1.05)	1.9 (1.25)	2.4 (1.35)	1.6 (1.31)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-0.35 (0.363)	-0.50 (0.233)	-0.17 (0.179)	-0.98 (0.129)	
95% CI [2]	-1.08, 0.39	-0.98, -0.03	-0.52, 0.19	-1.23, -0.72	
Difference (95% CI) in CFB [2]		-0.16 (-1.00, 0.69)		-0.81 (-1.24, -0.38)	
p-value [3]		0.707		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	2.0 (1.08)	1.7 (1.40)	2.2 (1.34)	1.7 (1.33)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	-0.38 (0.444)	-0.51 (0.287)	-0.38 (0.185)	-0.96 (0.133)	
95% CI [2]	-1.28, 0.53	-1.10, 0.07	-0.74, -0.01	-1.22, -0.69	
Difference (95% CI) in CFB [2]		-0.13 (-1.17, 0.90)		-0.58 (-1.02, -0.14)	
Hedges'G (95% CI) in CFB		-0.09 (-0.84, 0.64)		-0.44 (-0.80, -0.10)	
p-value [3]		0.793		0.011	
					0.320

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	2.4 (1.45)	2.1 (1.11)	2.3 (1.36)	2.5 (1.08)	
Median	3.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	2.4 (0.99)	1.7 (1.14)	2.0 (1.23)	1.9 (1.23)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	0.25 (0.437)	-0.35 (0.286)	-0.35 (0.148)	-0.64 (0.108)	
95% CI [2]	-0.63, 1.14	-0.93, 0.23	-0.65, -0.06	-0.85, -0.43	
Difference (95% CI) in CFB [2]		-0.60 (-1.63, 0.43)		-0.29 (-0.64, 0.07)	
p-value [3]		0.248		0.114	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	101	
Mean (StdDev)	1.9 (1.46)	1.9 (1.16)	1.9 (1.36)	1.7 (1.13)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	-0.29 (0.300)	-0.15 (0.196)	-0.45 (0.156)	-0.86 (0.114)	
95% CI [2]	-0.90, 0.32	-0.55, 0.24	-0.76, -0.14	-1.08, -0.63	
Difference (95% CI) in CFB [2]		0.13 (-0.57, 0.84)		-0.41 (-0.78, -0.03)	
p-value [3]		0.703		0.034	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	2.1 (1.50)	1.7 (1.20)	2.0 (1.33)	1.7 (1.23)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	-0.13 (0.306)	-0.36 (0.198)	-0.42 (0.193)	-0.84 (0.134)	
95% CI [2]	-0.75, 0.49	-0.76, 0.04	-0.81, -0.04	-1.11, -0.58	
Difference (95% CI) in CFB [2]		-0.23 (-0.95, 0.48)		-0.42 (-0.87, 0.04)	
p-value [3]		0.513		0.071	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	49	99	
Mean (StdDev)	2.0 (1.41)	1.5 (1.27)	2.1 (1.31)	1.6 (1.23)	
Median	2.0	1.5	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	12	25	49	94	
LS Mean (StdErr) [2]	-0.06 (0.371)	-0.49 (0.245)	-0.21 (0.182)	-0.91 (0.135)	
95% CI [2]	-0.82, 0.69	-0.98, 0.01	-0.57, 0.15	-1.18, -0.64	
Difference (95% CI) in CFB [2]		-0.42 (-1.29, 0.44)		-0.70 (-1.14, -0.26)	
p-value [3]		0.324		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	1.9 (1.03)	1.7 (1.20)	2.3 (1.41)	1.5 (1.25)	
Median	1.5	2.0	2.0	1.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-0.11 (0.355)	-0.27 (0.228)	-0.06 (0.187)	-1.05 (0.135)	
95% CI [2]	-0.84, 0.61	-0.73, 0.19	-0.43, 0.31	-1.31, -0.78	
Difference (95% CI) in CFB [2]		-0.16 (-0.98, 0.67)		-0.99 (-1.44, -0.54)	
p-value [3]		0.704		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	1.7 (1.11)	1.8 (1.18)	2.0 (1.39)	1.6 (1.30)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	-0.23 (0.332)	-0.16 (0.214)	-0.27 (0.189)	-0.96 (0.136)	
95% CI [2]	-0.90, 0.45	-0.60, 0.28	-0.64, 0.10	-1.23, -0.70	
Difference (95% CI) in CFB [2]		0.07 (-0.71, 0.84)		-0.69 (-1.15, -0.24)	
Hedges'G (95% CI) in CFB		0.06 (-0.67, 0.81)		-0.52 (-0.88, -0.17)	
p-value [3]		0.861		0.003	
					0.086

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	1.5 (1.71)	1.7 (1.39)	1.8 (1.51)	1.9 (1.51)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	1.9 (1.25)	1.5 (1.09)	1.7 (1.58)	1.5 (1.51)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	0.57 (0.277)	-0.23 (0.181)	-0.16 (0.150)	-0.37 (0.109)	
95% CI [2]	0.00, 1.13	-0.60, 0.14	-0.46, 0.13	-0.58, -0.15	
Difference (95% CI) in CFB [2]		-0.79 (-1.45, -0.14)		-0.21 (-0.57, 0.16)	
p-value [3]		0.019		0.263	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	101	
Mean (StdDev)	1.3 (1.29)	1.5 (1.24)	1.6 (1.63)	1.3 (1.42)	
Median	1.0	1.5	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	0.06 (0.256)	-0.16 (0.167)	-0.31 (0.162)	-0.52 (0.118)	
95% CI [2]	-0.45, 0.58	-0.50, 0.18	-0.63, 0.01	-0.76, -0.29	
Difference (95% CI) in CFB [2]		-0.22 (-0.83, 0.38)		-0.21 (-0.60, 0.17)	
p-value [3]		0.455		0.276	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	1.1 (1.19)	1.6 (1.17)	1.7 (1.37)	1.3 (1.43)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	-0.05 (0.413)	-0.03 (0.267)	-0.35 (0.189)	-0.65 (0.131)	
95% CI [2]	-0.89, 0.80	-0.57, 0.51	-0.73, 0.02	-0.91, -0.39	
Difference (95% CI) in CFB [2]		0.02 (-0.95, 0.98)		-0.30 (-0.74, 0.15)	
p-value [3]		0.974		0.190	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	49	98	
Mean (StdDev)	1.1 (1.10)	1.5 (1.27)	1.4 (1.47)	1.2 (1.34)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	12	25	49	93	
LS Mean (StdErr) [2]	0.11 (0.376)	-0.16 (0.248)	-0.39 (0.192)	-0.72 (0.142)	
95% CI [2]	-0.65, 0.88	-0.66, 0.35	-0.77, -0.01	-1.00, -0.44	
Difference (95% CI) in CFB [2]		-0.27 (-1.14, 0.60)		-0.33 (-0.80, 0.13)	
p-value [3]		0.535		0.158	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	1.1 (1.23)	1.4 (1.21)	1.5 (1.43)	1.3 (1.48)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-0.00 (0.414)	-0.24 (0.266)	-0.42 (0.205)	-0.66 (0.147)	
95% CI [2]	-0.85, 0.84	-0.78, 0.30	-0.83, -0.02	-0.95, -0.37	
Difference (95% CI) in CFB [2]		-0.24 (-1.20, 0.73)		-0.24 (-0.74, 0.25)	
p-value [3]		0.619		0.331	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	1.2 (0.93)	1.5 (1.29)	1.5 (1.52)	1.3 (1.44)	
Median	1.0	2.0	1.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	0.32 (0.427)	-0.11 (0.276)	-0.30 (0.191)	-0.58 (0.138)	
95% CI [2]	-0.55, 1.19	-0.67, 0.45	-0.68, 0.07	-0.85, -0.31	
Difference (95% CI) in CFB [2]		-0.43 (-1.43, 0.56)		-0.28 (-0.73, 0.18)	
Hedges'G (95% CI) in CFB		-0.31 (-1.07, 0.42)		-0.20 (-0.55, 0.14)	
p-value [3]		0.384		0.236	
					0.903

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	2.1 (1.32)	2.2 (1.12)	2.2 (1.30)	2.3 (1.19)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	1.9 (1.10)	1.6 (1.15)	1.8 (1.26)	1.8 (1.20)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	-0.14 (0.272)	-0.59 (0.178)	-0.46 (0.124)	-0.48 (0.090)	
95% CI [2]	-0.69, 0.41	-0.95, -0.23	-0.71, -0.22	-0.66, -0.31	
Difference (95% CI) in CFB [2]		-0.45 (-1.09, 0.19)		-0.02 (-0.32, 0.28)	
p-value [3]		0.164		0.886	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	101	
Mean (StdDev)	1.9 (1.30)	1.6 (1.13)	1.9 (1.29)	1.6 (1.29)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	-0.11 (0.271)	-0.66 (0.177)	-0.37 (0.149)	-0.80 (0.108)	
95% CI [2]	-0.65, 0.44	-1.02, -0.30	-0.66, -0.08	-1.02, -0.59	
Difference (95% CI) in CFB [2]		-0.56 (-1.19, 0.08)		-0.43 (-0.79, -0.08)	
p-value [3]		0.087		0.017	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	1.8 (1.21)	1.7 (1.09)	1.9 (1.18)	1.5 (1.21)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	0.29 (0.259)	-0.67 (0.168)	-0.51 (0.150)	-0.86 (0.104)	
95% CI [2]	-0.24, 0.82	-1.01, -0.33	-0.81, -0.21	-1.06, -0.65	
Difference (95% CI) in CFB [2]		-0.96 (-1.57, -0.36)		-0.35 (-0.70, 0.01)	
p-value [3]		0.003		0.055	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	49	99	
Mean (StdDev)	1.5 (1.09)	1.4 (1.17)	1.8 (1.25)	1.5 (1.24)	
Median	1.0	1.5	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	12	25	49	94	
LS Mean (StdErr) [2]	-0.58 (0.277)	-0.91 (0.182)	-0.43 (0.162)	-0.97 (0.120)	
95% CI [2]	-1.14, -0.02	-1.28, -0.54	-0.75, -0.11	-1.21, -0.74	
Difference (95% CI) in CFB [2]		-0.33 (-0.97, 0.31)		-0.54 (-0.93, -0.15)	
p-value [3]		0.305		0.007	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	1.8 (1.19)	1.5 (1.22)	2.1 (1.22)	1.5 (1.35)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-0.16 (0.259)	-0.72 (0.166)	-0.17 (0.171)	-0.90 (0.123)	
95% CI [2]	-0.69, 0.36	-1.06, -0.38	-0.51, 0.17	-1.14, -0.65	
Difference (95% CI) in CFB [2]		-0.56 (-1.16, 0.05)		-0.73 (-1.14, -0.32)	
p-value [3]		0.069		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	1.7 (1.03)	1.7 (1.34)	1.9 (1.44)	1.4 (1.29)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	-0.06 (0.285)	-0.49 (0.184)	-0.38 (0.161)	-0.99 (0.116)	
95% CI [2]	-0.64, 0.52	-0.86, -0.11	-0.70, -0.07	-1.22, -0.77	
Difference (95% CI) in CFB [2]		-0.43 (-1.09, 0.24)		-0.61 (-1.00, -0.23)	
Hedges'G (95% CI) in CFB		-0.46 (-1.24, 0.26)		-0.54 (-0.90, -0.19)	
p-value [3]		0.201		0.002	
					0.615

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	2.0 (1.22)	2.0 (1.32)	1.9 (1.44)	2.1 (1.29)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	1.5 (1.13)	1.6 (1.19)	1.5 (1.22)	1.6 (1.28)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	-0.39 (0.316)	-0.41 (0.207)	-0.41 (0.139)	-0.47 (0.101)	
95% CI [2]	-1.04, 0.25	-0.83, 0.01	-0.68, -0.13	-0.67, -0.27	
Difference (95% CI) in CFB [2]		-0.01 (-0.76, 0.73)		-0.06 (-0.39, 0.28)	
p-value [3]		0.969		0.728	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	101	
Mean (StdDev)	1.5 (1.06)	1.5 (1.14)	1.6 (1.34)	1.4 (1.31)	
Median	1.0	1.0	1.5	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	-0.34 (0.306)	-0.51 (0.200)	-0.28 (0.144)	-0.64 (0.105)	
95% CI [2]	-0.96, 0.28	-0.92, -0.11	-0.56, 0.01	-0.85, -0.43	
Difference (95% CI) in CFB [2]		-0.17 (-0.89, 0.55)		-0.36 (-0.71, -0.01)	
p-value [3]		0.631		0.041	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	1.5 (0.97)	1.5 (1.22)	1.6 (1.21)	1.3 (1.24)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	-0.37 (0.360)	-0.63 (0.233)	-0.45 (0.147)	-0.78 (0.102)	
95% CI [2]	-1.10, 0.36	-1.11, -0.16	-0.74, -0.16	-0.99, -0.58	
Difference (95% CI) in CFB [2]		-0.26 (-1.10, 0.58)		-0.34 (-0.68, 0.01)	
p-value [3]		0.529		0.056	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	49	99	
Mean (StdDev)	1.4 (1.09)	1.3 (1.09)	1.6 (1.37)	1.3 (1.25)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	12	25	49	94	
LS Mean (StdErr) [2]	-0.37 (0.334)	-0.71 (0.220)	-0.33 (0.163)	-0.86 (0.121)	
95% CI [2]	-1.05, 0.31	-1.15, -0.26	-0.65, -0.01	-1.10, -0.62	
Difference (95% CI) in CFB [2]		-0.33 (-1.11, 0.44)		-0.53 (-0.92, -0.13)	
p-value [3]		0.387		0.009	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	1.2 (1.12)	1.4 (1.12)	1.8 (1.29)	1.3 (1.36)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-0.60 (0.368)	-0.59 (0.236)	-0.14 (0.158)	-0.86 (0.114)	
95% CI [2]	-1.35, 0.14	-1.07, -0.11	-0.46, 0.17	-1.09, -0.64	
Difference (95% CI) in CFB [2]		0.01 (-0.85, 0.86)		-0.72 (-1.10, -0.34)	
p-value [3]		0.981		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	1.5 (1.13)	1.4 (1.33)	1.5 (1.39)	1.2 (1.32)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	-0.04 (0.383)	-0.52 (0.247)	-0.32 (0.156)	-0.84 (0.112)	
95% CI [2]	-0.82, 0.74	-1.03, -0.02	-0.63, -0.01	-1.06, -0.62	
Difference (95% CI) in CFB [2]		-0.48 (-1.37, 0.41)		-0.52 (-0.89, -0.14)	
Hedges'G (95% CI) in CFB		-0.38 (-1.15, 0.34)		-0.47 (-0.83, -0.12)	
p-value [3]		0.283		0.007	
					0.940

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	2.7 (1.11)	2.7 (1.27)	3.1 (0.89)	2.9 (0.97)	
Median	3.0	3.0	3.0	3.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	2.4 (1.18)	2.3 (0.98)	2.6 (1.04)	2.5 (1.03)	
Median	3.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	-0.46 (0.308)	-0.52 (0.201)	-0.50 (0.123)	-0.39 (0.089)	
95% CI [2]	-1.08, 0.17	-0.92, -0.11	-0.74, -0.26	-0.57, -0.22	
Difference (95% CI) in CFB [2]		-0.06 (-0.78, 0.67)		0.10 (-0.19, 0.40)	
p-value [3]		0.874		0.486	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	101	
Mean (StdDev)	2.5 (1.25)	2.3 (1.32)	2.6 (1.03)	2.2 (1.11)	
Median	3.0	2.5	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	-0.11 (0.235)	-0.36 (0.153)	-0.54 (0.145)	-0.75 (0.105)	
95% CI [2]	-0.59, 0.36	-0.67, -0.05	-0.83, -0.26	-0.96, -0.54	
Difference (95% CI) in CFB [2]		-0.24 (-0.80, 0.31)		-0.21 (-0.55, 0.14)	
p-value [3]		0.377		0.241	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	2.5 (1.39)	2.4 (1.44)	2.3 (1.22)	2.2 (1.17)	
Median	3.0	2.5	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	-0.22 (0.366)	-0.27 (0.237)	-0.80 (0.155)	-0.67 (0.108)	
95% CI [2]	-0.97, 0.52	-0.75, 0.21	-1.11, -0.49	-0.89, -0.46	
Difference (95% CI) in CFB [2]		-0.05 (-0.91, 0.81)		0.13 (-0.24, 0.49)	
p-value [3]		0.906		0.501	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	99	
Mean (StdDev)	2.4 (1.15)	1.9 (1.34)	2.5 (1.07)	2.1 (1.26)	
Median	2.0	2.0	2.5	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	12	25	50	94	
LS Mean (StdErr) [2]	-0.40 (0.369)	-0.91 (0.243)	-0.58 (0.167)	-0.84 (0.125)	
95% CI [2]	-1.15, 0.35	-1.40, -0.41	-0.91, -0.25	-1.08, -0.59	
Difference (95% CI) in CFB [2]		-0.51 (-1.37, 0.35)		-0.26 (-0.66, 0.15)	
p-value [3]		0.235		0.209	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	2.4 (1.15)	2.4 (1.21)	2.5 (1.24)	2.0 (1.24)	
Median	2.0	3.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-0.29 (0.373)	-0.36 (0.240)	-0.49 (0.166)	-0.87 (0.119)	
95% CI [2]	-1.05, 0.46	-0.85, 0.12	-0.81, -0.16	-1.10, -0.63	
Difference (95% CI) in CFB [2]		-0.07 (-0.93, 0.80)		-0.38 (-0.78, 0.02)	
p-value [3]		0.876		0.061	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	2.2 (1.30)	2.3 (1.24)	2.5 (1.08)	2.1 (1.15)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	-0.33 (0.406)	-0.44 (0.263)	-0.52 (0.156)	-0.78 (0.113)	
95% CI [2]	-1.15, 0.50	-0.98, 0.09	-0.83, -0.21	-1.01, -0.56	
Difference (95% CI) in CFB [2]		-0.12 (-1.07, 0.83)		-0.26 (-0.64, 0.11)	
Hedges'G (95% CI) in CFB		-0.09 (-0.83, 0.65)		-0.24 (-0.59, 0.11)	
p-value [3]		0.803		0.170	
					0.734

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	2.8 (1.28)	2.6 (0.97)	2.3 (1.51)	2.4 (1.26)	
Median	3.0	3.0	3.0	2.0	
Min, Max	0, 4	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	2.5 (0.83)	2.1 (1.43)	2.1 (1.36)	1.9 (1.29)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	-0.71 (0.316)	-0.44 (0.206)	-0.22 (0.142)	-0.52 (0.103)	
95% CI [2]	-1.35, -0.07	-0.86, -0.02	-0.50, 0.06	-0.73, -0.32	
Difference (95% CI) in CFB [2]		0.27 (-0.47, 1.02)		-0.30 (-0.64, 0.04)	
p-value [3]		0.463		0.081	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	101	
Mean (StdDev)	2.4 (1.12)	2.1 (1.13)	2.2 (1.30)	1.7 (1.29)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	-0.67 (0.319)	-0.56 (0.209)	-0.15 (0.163)	-0.72 (0.119)	
95% CI [2]	-1.32, -0.03	-0.99, -0.14	-0.47, 0.17	-0.95, -0.48	
Difference (95% CI) in CFB [2]		0.11 (-0.64, 0.86)		-0.57 (-0.96, -0.17)	
p-value [3]		0.769		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	2.5 (1.13)	2.4 (1.24)	1.9 (1.41)	1.7 (1.38)	
Median	2.0	3.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	-0.57 (0.319)	-0.21 (0.206)	-0.46 (0.157)	-0.87 (0.109)	
95% CI [2]	-1.22, 0.08	-0.63, 0.21	-0.78, -0.15	-1.09, -0.66	
Difference (95% CI) in CFB [2]		0.36 (-0.39, 1.10)		-0.41 (-0.78, -0.04)	
p-value [3]		0.337		0.031	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	99	
Mean (StdDev)	2.4 (1.08)	2.0 (1.44)	1.9 (1.58)	1.7 (1.41)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	12	25	50	94	
LS Mean (StdErr) [2]	-0.76 (0.306)	-0.56 (0.201)	-0.42 (0.166)	-0.88 (0.124)	
95% CI [2]	-1.38, -0.13	-0.97, -0.15	-0.75, -0.10	-1.12, -0.63	
Difference (95% CI) in CFB [2]		0.20 (-0.51, 0.91)		-0.45 (-0.85, -0.05)	
p-value [3]		0.574		0.028	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	2.6 (0.76)	1.9 (1.41)	2.1 (1.46)	1.5 (1.33)	
Median	3.0	2.0	2.0	1.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-0.59 (0.336)	-0.63 (0.216)	-0.18 (0.162)	-0.98 (0.117)	
95% CI [2]	-1.27, 0.10	-1.06, -0.19	-0.50, 0.14	-1.21, -0.74	
Difference (95% CI) in CFB [2]		-0.04 (-0.82, 0.74)		-0.80 (-1.19, -0.41)	
p-value [3]		0.919		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	2.4 (1.04)	1.9 (1.36)	1.9 (1.55)	1.4 (1.39)	
Median	2.0	2.0	2.0	1.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	-0.58 (0.394)	-0.63 (0.255)	-0.42 (0.169)	-1.01 (0.122)	
95% CI [2]	-1.38, 0.22	-1.15, -0.11	-0.76, -0.09	-1.25, -0.77	
Difference (95% CI) in CFB [2]		-0.05 (-0.97, 0.87)		-0.59 (-1.00, -0.19)	
Hedges'G (95% CI) in CFB		-0.04 (-0.78, 0.70)		-0.49 (-0.85, -0.15)	
p-value [3]		0.907		0.005	
					0.302

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	2.9 (1.12)	3.0 (0.92)	2.8 (1.13)	2.9 (1.01)	
Median	3.0	3.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	2.3 (1.10)	2.3 (1.35)	2.3 (1.14)	2.2 (1.20)	
Median	2.0	3.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	-0.75 (0.305)	-0.67 (0.199)	-0.55 (0.134)	-0.71 (0.097)	
95% CI [2]	-1.37, -0.14	-1.07, -0.26	-0.81, -0.28	-0.91, -0.52	
Difference (95% CI) in CFB [2]		0.09 (-0.63, 0.81)		-0.17 (-0.49, 0.15)	
p-value [3]		0.810		0.306	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	101	
Mean (StdDev)	2.6 (1.45)	2.2 (1.11)	2.3 (1.12)	1.9 (1.21)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	-0.37 (0.305)	-0.82 (0.199)	-0.49 (0.153)	-0.95 (0.111)	
95% CI [2]	-0.99, 0.25	-1.23, -0.42	-0.79, -0.19	-1.17, -0.73	
Difference (95% CI) in CFB [2]		-0.45 (-1.17, 0.27)		-0.46 (-0.83, -0.09)	
p-value [3]		0.214		0.014	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	2.4 (1.12)	2.4 (0.97)	2.5 (1.18)	1.9 (1.27)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	-0.51 (0.237)	-0.74 (0.153)	-0.43 (0.168)	-0.99 (0.117)	
95% CI [2]	-0.99, -0.03	-1.05, -0.42	-0.76, -0.10	-1.22, -0.75	
Difference (95% CI) in CFB [2]		-0.23 (-0.78, 0.33)		-0.55 (-0.95, -0.16)	
p-value [3]		0.409		0.007	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	98	
Mean (StdDev)	2.1 (1.17)	2.1 (1.32)	2.4 (1.19)	1.9 (1.15)	
Median	2.0	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	12	25	50	93	
LS Mean (StdErr) [2]	-0.64 (0.295)	-0.83 (0.194)	-0.43 (0.156)	-1.03 (0.117)	
95% CI [2]	-1.24, -0.04	-1.23, -0.44	-0.74, -0.13	-1.26, -0.80	
Difference (95% CI) in CFB [2]		-0.19 (-0.88, 0.49)		-0.59 (-0.97, -0.21)	
p-value [3]		0.571		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	2.0 (1.04)	2.0 (1.43)	2.6 (1.16)	1.8 (1.27)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-0.72 (0.320)	-0.96 (0.205)	-0.20 (0.167)	-1.06 (0.120)	
95% CI [2]	-1.37, -0.07	-1.38, -0.54	-0.53, 0.13	-1.30, -0.82	
Difference (95% CI) in CFB [2]		-0.24 (-0.98, 0.50)		-0.86 (-1.26, -0.46)	
p-value [3]		0.515		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	2.4 (1.26)	2.1 (1.38)	2.2 (1.33)	1.8 (1.26)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	-0.35 (0.333)	-0.83 (0.215)	-0.52 (0.164)	-1.02 (0.118)	
95% CI [2]	-1.03, 0.32	-1.27, -0.39	-0.85, -0.20	-1.26, -0.79	
Difference (95% CI) in CFB [2]		-0.48 (-1.25, 0.30)		-0.50 (-0.90, -0.11)	
Hedges'G (95% CI) in CFB		-0.43 (-1.21, 0.28)		-0.43 (-0.79, -0.09)	
p-value [3]		0.222		0.013	
					0.992

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	3.0 (0.91)	3.0 (1.02)	3.1 (0.94)	3.1 (0.95)	
Median	3.0	3.0	3.0	3.0	
Min, Max	2, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	2.3 (0.90)	2.5 (0.94)	2.6 (1.01)	2.3 (1.12)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	-0.50 (0.251)	-0.47 (0.164)	-0.45 (0.133)	-0.84 (0.096)	
95% CI [2]	-1.01, 0.01	-0.81, -0.14	-0.71, -0.19	-1.03, -0.65	
Difference (95% CI) in CFB [2]		0.02 (-0.57, 0.62)		-0.39 (-0.71, -0.07)	
p-value [3]		0.935		0.016	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	101	
Mean (StdDev)	2.5 (1.30)	2.3 (1.06)	2.5 (1.04)	2.0 (1.20)	
Median	2.0	2.5	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	-0.29 (0.329)	-0.69 (0.215)	-0.64 (0.155)	-1.10 (0.113)	
95% CI [2]	-0.96, 0.38	-1.13, -0.26	-0.95, -0.34	-1.32, -0.87	
Difference (95% CI) in CFB [2]		-0.40 (-1.18, 0.37)		-0.46 (-0.83, -0.08)	
p-value [3]		0.301		0.016	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	2.4 (1.19)	2.4 (1.02)	2.4 (1.16)	2.0 (1.16)	
Median	3.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	-0.59 (0.357)	-0.73 (0.231)	-0.70 (0.153)	-1.21 (0.106)	
95% CI [2]	-1.32, 0.14	-1.20, -0.26	-1.01, -0.40	-1.42, -1.00	
Difference (95% CI) in CFB [2]		-0.14 (-0.97, 0.69)		-0.51 (-0.87, -0.15)	
p-value [3]		0.733		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	99	
Mean (StdDev)	2.0 (1.04)	2.3 (1.16)	2.5 (1.34)	2.0 (1.20)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	12	25	50	94	
LS Mean (StdErr) [2]	-0.93 (0.326)	-0.69 (0.215)	-0.57 (0.166)	-1.14 (0.124)	
95% CI [2]	-1.60, -0.27	-1.13, -0.26	-0.90, -0.24	-1.38, -0.89	
Difference (95% CI) in CFB [2]		0.24 (-0.52, 1.00)		-0.57 (-0.97, -0.17)	
p-value [3]		0.521		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	1.9 (0.83)	2.2 (1.28)	2.7 (1.16)	1.9 (1.26)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-1.00 (0.326)	-0.81 (0.209)	-0.36 (0.170)	-1.20 (0.122)	
95% CI [2]	-1.66, -0.34	-1.23, -0.38	-0.70, -0.02	-1.44, -0.96	
Difference (95% CI) in CFB [2]		0.19 (-0.57, 0.95)		-0.84 (-1.25, -0.43)	
p-value [3]		0.613		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	2.1 (1.26)	2.3 (1.43)	2.4 (1.35)	1.9 (1.18)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	-0.71 (0.418)	-0.71 (0.270)	-0.63 (0.164)	-1.20 (0.118)	
95% CI [2]	-1.57, 0.14	-1.26, -0.16	-0.96, -0.31	-1.43, -0.96	
Difference (95% CI) in CFB [2]		0.00 (-0.97, 0.98)		-0.57 (-0.96, -0.17)	
Hedges'G (95% CI) in CFB		0.00 (-0.74, 0.74)		-0.49 (-0.84, -0.14)	
p-value [3]		0.992		0.005	
					0.206

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	2.2 (1.34)	1.8 (1.52)	2.2 (1.53)	1.8 (1.45)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	2.1 (1.39)	2.0 (1.47)	1.9 (1.45)	1.3 (1.34)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	0.26 (0.381)	0.22 (0.249)	-0.34 (0.156)	-0.54 (0.113)	
95% CI [2]	-0.51, 1.04	-0.29, 0.72	-0.64, -0.03	-0.76, -0.32	
Difference (95% CI) in CFB [2]		-0.05 (-0.95, 0.85)		-0.20 (-0.58, 0.17)	
p-value [3]		0.915		0.285	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	101	
Mean (StdDev)	1.7 (1.35)	1.9 (1.24)	2.0 (1.41)	1.2 (1.37)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	-0.22 (0.389)	0.04 (0.254)	-0.16 (0.176)	-0.62 (0.128)	
95% CI [2]	-1.01, 0.57	-0.48, 0.55	-0.51, 0.19	-0.88, -0.37	
Difference (95% CI) in CFB [2]		0.26 (-0.66, 1.18)		-0.46 (-0.88, -0.04)	
p-value [3]		0.572		0.033	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	1.9 (1.04)	1.9 (1.41)	1.8 (1.35)	1.3 (1.36)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	0.05 (0.419)	0.05 (0.271)	-0.42 (0.171)	-0.54 (0.118)	
95% CI [2]	-0.80, 0.90	-0.50, 0.61	-0.75, -0.08	-0.77, -0.30	
Difference (95% CI) in CFB [2]		0.01 (-0.97, 0.98)		-0.12 (-0.53, 0.28)	
p-value [3]		0.990		0.550	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	99	
Mean (StdDev)	1.6 (1.08)	1.9 (1.32)	1.8 (1.43)	1.2 (1.35)	
Median	1.5	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	12	25	50	94	
LS Mean (StdErr) [2]	-0.25 (0.363)	0.19 (0.239)	-0.33 (0.190)	-0.62 (0.142)	
95% CI [2]	-0.99, 0.49	-0.30, 0.68	-0.70, 0.05	-0.90, -0.34	
Difference (95% CI) in CFB [2]		0.44 (-0.40, 1.28)		-0.29 (-0.75, 0.17)	
p-value [3]		0.298		0.214	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	1.4 (1.22)	1.7 (1.30)	2.0 (1.49)	1.2 (1.32)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-0.54 (0.409)	0.03 (0.263)	-0.22 (0.194)	-0.63 (0.139)	
95% CI [2]	-1.37, 0.29	-0.50, 0.57	-0.60, 0.16	-0.91, -0.35	
Difference (95% CI) in CFB [2]		0.58 (-0.38, 1.53)		-0.41 (-0.87, 0.06)	
p-value [3]		0.228		0.085	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	1.8 (1.28)	1.9 (1.45)	1.9 (1.55)	1.1 (1.23)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	0.16 (0.448)	0.10 (0.289)	-0.23 (0.190)	-0.65 (0.137)	
95% CI [2]	-0.75, 1.07	-0.49, 0.69	-0.60, 0.15	-0.93, -0.38	
Difference (95% CI) in CFB [2]		-0.05 (-1.10, 0.99)		-0.43 (-0.88, 0.03)	
Hedges'G (95% CI) in CFB		-0.04 (-0.78, 0.70)		-0.32 (-0.67, 0.03)	
p-value [3]		0.916		0.067	
					0.477

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	2.2 (1.41)	2.0 (1.51)	1.6 (1.20)	1.6 (1.25)	
Median	2.0	2.0	1.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	1.9 (0.88)	1.6 (1.40)	1.4 (1.14)	1.3 (1.19)	
Median	2.0	1.0	1.0	1.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	-0.34 (0.244)	-0.57 (0.159)	-0.21 (0.119)	-0.35 (0.087)	
95% CI [2]	-0.83, 0.16	-0.89, -0.24	-0.45, 0.02	-0.52, -0.18	
Difference (95% CI) in CFB [2]		-0.23 (-0.80, 0.35)		-0.14 (-0.43, 0.15)	
p-value [3]		0.423		0.342	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	101	
Mean (StdDev)	1.3 (1.05)	1.3 (1.28)	1.5 (1.21)	1.0 (1.14)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	-0.77 (0.359)	-0.71 (0.234)	-0.04 (0.152)	-0.60 (0.111)	
95% CI [2]	-1.50, -0.04	-1.19, -0.24	-0.34, 0.26	-0.82, -0.38	
Difference (95% CI) in CFB [2]		0.06 (-0.79, 0.90)		-0.56 (-0.92, -0.19)	
p-value [3]		0.891		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	1.6 (1.12)	1.2 (1.18)	1.5 (1.21)	1.0 (1.16)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	-0.45 (0.334)	-0.75 (0.216)	-0.10 (0.169)	-0.62 (0.117)	
95% CI [2]	-1.13, 0.23	-1.19, -0.31	-0.43, 0.24	-0.85, -0.39	
Difference (95% CI) in CFB [2]		-0.31 (-1.08, 0.47)		-0.52 (-0.92, -0.12)	
p-value [3]		0.431		0.011	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	99	
Mean (StdDev)	1.5 (0.85)	1.2 (1.30)	1.5 (1.23)	0.9 (1.14)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	12	25	50	94	
LS Mean (StdErr) [2]	-0.73 (0.324)	-0.80 (0.214)	-0.12 (0.153)	-0.68 (0.115)	
95% CI [2]	-1.39, -0.07	-1.23, -0.36	-0.42, 0.19	-0.91, -0.46	
Difference (95% CI) in CFB [2]		-0.06 (-0.82, 0.69)		-0.57 (-0.94, -0.20)	
p-value [3]		0.863		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	1.4 (1.01)	1.3 (1.32)	1.5 (1.22)	1.0 (1.14)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-0.68 (0.356)	-0.64 (0.229)	-0.05 (0.150)	-0.62 (0.108)	
95% CI [2]	-1.40, 0.04	-1.10, -0.18	-0.35, 0.25	-0.84, -0.41	
Difference (95% CI) in CFB [2]		0.04 (-0.79, 0.87)		-0.57 (-0.93, -0.21)	
p-value [3]		0.921		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	1.2 (0.93)	1.2 (1.33)	1.3 (1.17)	0.9 (1.07)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	-0.57 (0.407)	-0.57 (0.263)	-0.26 (0.144)	-0.65 (0.104)	
95% CI [2]	-1.40, 0.26	-1.11, -0.03	-0.55, 0.02	-0.86, -0.45	
Difference (95% CI) in CFB [2]		0.00 (-0.95, 0.95)		-0.39 (-0.74, -0.04)	
Hedges'G (95% CI) in CFB		0.00 (-0.74, 0.74)		-0.38 (-0.74, -0.04)	
p-value [3]		0.997		0.027	
					0.230

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	1.4 (1.26)	1.4 (1.50)	1.2 (1.29)	1.4 (1.45)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	1.4 (1.40)	1.3 (1.40)	1.1 (1.32)	1.2 (1.34)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	-0.14 (0.347)	-0.13 (0.227)	-0.02 (0.138)	-0.19 (0.100)	
95% CI [2]	-0.85, 0.56	-0.59, 0.33	-0.29, 0.25	-0.38, 0.01	
Difference (95% CI) in CFB [2]		0.01 (-0.81, 0.83)		-0.17 (-0.50, 0.17)	
p-value [3]		0.972		0.324	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	101	
Mean (StdDev)	1.2 (1.21)	1.0 (1.15)	0.9 (1.19)	0.9 (1.21)	
Median	1.0	1.0	0.5	0.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	-0.02 (0.386)	-0.32 (0.252)	-0.18 (0.151)	-0.44 (0.110)	
95% CI [2]	-0.80, 0.76	-0.83, 0.19	-0.48, 0.11	-0.66, -0.23	
Difference (95% CI) in CFB [2]		-0.30 (-1.21, 0.61)		-0.26 (-0.62, 0.10)	
p-value [3]		0.513		0.160	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	1.3 (1.25)	0.8 (0.94)	1.3 (1.28)	1.0 (1.24)	
Median	1.0	0.0	1.0	1.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	-0.17 (0.308)	-0.66 (0.199)	0.08 (0.170)	-0.39 (0.118)	
95% CI [2]	-0.79, 0.46	-1.07, -0.25	-0.26, 0.41	-0.63, -0.16	
Difference (95% CI) in CFB [2]		-0.49 (-1.21, 0.22)		-0.47 (-0.87, -0.07)	
p-value [3]		0.171		0.023	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	99	
Mean (StdDev)	1.1 (1.29)	0.9 (1.14)	1.2 (1.25)	0.8 (1.21)	
Median	1.0	0.0	1.0	0.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	12	25	50	94	
LS Mean (StdErr) [2]	-0.31 (0.326)	-0.43 (0.215)	0.01 (0.148)	-0.54 (0.111)	
95% CI [2]	-0.97, 0.36	-0.86, 0.01	-0.28, 0.31	-0.76, -0.33	
Difference (95% CI) in CFB [2]		-0.12 (-0.88, 0.63)		-0.56 (-0.92, -0.20)	
p-value [3]		0.743		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	1.2 (1.19)	0.8 (1.08)	1.1 (1.25)	0.9 (1.18)	
Median	1.0	0.0	1.0	0.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-0.24 (0.310)	-0.57 (0.199)	-0.01 (0.160)	-0.51 (0.115)	
95% CI [2]	-0.87, 0.39	-0.98, -0.17	-0.32, 0.31	-0.73, -0.28	
Difference (95% CI) in CFB [2]		-0.33 (-1.06, 0.39)		-0.50 (-0.88, -0.12)	
p-value [3]		0.353		0.011	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	1.0 (0.91)	0.8 (1.31)	1.1 (1.25)	0.9 (1.19)	
Median	1.0	0.0	1.0	0.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	-0.12 (0.352)	-0.27 (0.227)	-0.00 (0.153)	-0.46 (0.110)	
95% CI [2]	-0.83, 0.60	-0.74, 0.19	-0.31, 0.30	-0.67, -0.24	
Difference (95% CI) in CFB [2]		-0.15 (-0.98, 0.67)		-0.45 (-0.82, -0.08)	
Hedges'G (95% CI) in CFB		-0.13 (-0.88, 0.60)		-0.41 (-0.77, -0.07)	
p-value [3]		0.703		0.017	
					0.444

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	2.2 (0.80)	2.2 (1.39)	1.9 (1.22)	1.8 (1.27)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	1.1 (1.03)	1.6 (1.28)	1.6 (1.30)	1.3 (1.24)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	-0.98 (0.271)	-0.63 (0.177)	-0.32 (0.149)	-0.52 (0.108)	
95% CI [2]	-1.53, -0.43	-0.99, -0.27	-0.61, -0.02	-0.73, -0.31	
Difference (95% CI) in CFB [2]		0.35 (-0.29, 0.99)		-0.20 (-0.56, 0.16)	
p-value [3]		0.269		0.268	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	101	
Mean (StdDev)	1.5 (0.83)	1.5 (1.07)	1.5 (1.20)	1.2 (1.15)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	-0.53 (0.228)	-0.73 (0.149)	-0.38 (0.149)	-0.55 (0.108)	
95% CI [2]	-1.00, -0.07	-1.03, -0.43	-0.67, -0.08	-0.77, -0.34	
Difference (95% CI) in CFB [2]		-0.20 (-0.73, 0.34)		-0.18 (-0.53, 0.18)	
p-value [3]		0.464		0.331	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	1.3 (1.03)	1.7 (1.16)	1.5 (1.30)	1.2 (1.20)	
Median	1.0	2.0	1.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	-0.77 (0.383)	-0.68 (0.248)	-0.32 (0.167)	-0.65 (0.116)	
95% CI [2]	-1.55, 0.01	-1.18, -0.17	-0.65, 0.01	-0.88, -0.42	
Difference (95% CI) in CFB [2]		0.09 (-0.80, 0.99)		-0.34 (-0.73, 0.06)	
p-value [3]		0.832		0.093	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	99	
Mean (StdDev)	1.3 (0.91)	1.6 (1.03)	1.4 (1.40)	1.0 (1.18)	
Median	1.0	2.0	1.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C5D1 CFB					
n	12	25	50	94	
LS Mean (StdErr) [2]	-0.66 (0.306)	-0.64 (0.202)	-0.37 (0.159)	-0.83 (0.118)	
95% CI [2]	-1.28, -0.04	-1.05, -0.23	-0.68, -0.06	-1.07, -0.60	
Difference (95% CI) in CFB [2]		0.02 (-0.69, 0.74)		-0.46 (-0.85, -0.08)	
p-value [3]		0.945		0.018	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	1.1 (1.07)	1.3 (1.06)	1.6 (1.33)	0.9 (1.11)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-0.84 (0.364)	-0.92 (0.233)	-0.19 (0.162)	-1.01 (0.116)	
95% CI [2]	-1.58, -0.10	-1.40, -0.45	-0.50, 0.13	-1.24, -0.78	
Difference (95% CI) in CFB [2]		-0.09 (-0.93, 0.76)		-0.83 (-1.21, -0.44)	
p-value [3]		0.836		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	1.2 (1.09)	1.7 (1.28)	1.6 (1.43)	0.9 (1.15)	
Median	1.0	2.0	2.0	0.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	-0.56 (0.436)	-0.47 (0.282)	-0.25 (0.175)	-0.88 (0.126)	
95% CI [2]	-1.45, 0.33	-1.04, 0.11	-0.59, 0.10	-1.13, -0.63	
Difference (95% CI) in CFB [2]		0.09 (-0.93, 1.11)		-0.63 (-1.05, -0.21)	
Hedges'G (95% CI) in CFB		0.06 (-0.67, 0.81)		-0.51 (-0.87, -0.16)	
p-value [3]		0.860		0.003	
					0.142

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	2.0 (1.00)	2.4 (1.37)	2.4 (1.02)	2.2 (1.23)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	1.5 (0.92)	1.9 (1.30)	1.8 (1.18)	1.5 (1.27)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	-0.37 (0.245)	-0.50 (0.160)	-0.58 (0.148)	-0.66 (0.108)	
95% CI [2]	-0.87, 0.12	-0.82, -0.17	-0.87, -0.28	-0.88, -0.45	
Difference (95% CI) in CFB [2]		-0.12 (-0.70, 0.45)		-0.09 (-0.44, 0.27)	
p-value [3]		0.665		0.629	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	101	
Mean (StdDev)	1.4 (1.06)	1.7 (1.15)	1.8 (1.14)	1.3 (1.11)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	-0.53 (0.304)	-0.73 (0.199)	-0.48 (0.158)	-0.80 (0.115)	
95% CI [2]	-1.15, 0.08	-1.13, -0.33	-0.79, -0.16	-1.02, -0.57	
Difference (95% CI) in CFB [2]		-0.20 (-0.91, 0.52)		-0.32 (-0.70, 0.06)	
p-value [3]		0.583		0.098	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	104	
Mean (StdDev)	1.1 (0.76)	1.8 (1.28)	1.9 (1.18)	1.3 (1.25)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	11	24	46	100	
LS Mean (StdErr) [2]	-0.87 (0.359)	-0.81 (0.232)	-0.49 (0.168)	-0.90 (0.116)	
95% CI [2]	-1.60, -0.14	-1.29, -0.34	-0.82, -0.15	-1.13, -0.67	
Difference (95% CI) in CFB [2]		0.06 (-0.78, 0.90)		-0.41 (-0.81, -0.02)	
p-value [3]		0.886		0.042	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	99	
Mean (StdDev)	1.1 (0.66)	1.6 (1.17)	1.7 (1.43)	1.3 (1.22)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C5D1 CFB					
n	12	25	50	94	
LS Mean (StdErr) [2]	-0.69 (0.325)	-0.85 (0.214)	-0.64 (0.176)	-0.93 (0.131)	
95% CI [2]	-1.35, -0.03	-1.29, -0.42	-0.99, -0.30	-1.19, -0.67	
Difference (95% CI) in CFB [2]		-0.17 (-0.92, 0.59)		-0.29 (-0.71, 0.14)	
p-value [3]		0.656		0.188	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	1.1 (1.07)	1.6 (1.25)	1.8 (1.27)	1.2 (1.25)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-0.84 (0.406)	-0.88 (0.260)	-0.53 (0.169)	-1.06 (0.122)	
95% CI [2]	-1.66, -0.01	-1.40, -0.35	-0.86, -0.20	-1.30, -0.82	
Difference (95% CI) in CFB [2]		-0.04 (-0.98, 0.90)		-0.53 (-0.93, -0.12)	
p-value [3]		0.933		0.011	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	1.1 (0.76)	1.7 (1.37)	1.6 (1.30)	1.2 (1.20)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	-0.58 (0.342)	-0.64 (0.221)	-0.73 (0.178)	-0.93 (0.128)	
95% CI [2]	-1.28, 0.12	-1.09, -0.19	-1.08, -0.38	-1.18, -0.67	
Difference (95% CI) in CFB [2]		-0.06 (-0.86, 0.73)		-0.20 (-0.62, 0.23)	
Hedges'G (95% CI) in CFB		-0.06 (-0.80, 0.68)		-0.15 (-0.50, 0.19)	
p-value [3]		0.871		0.366	
					0.831

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	2.4 (1.26)	2.7 (1.23)	2.7 (1.09)	2.6 (1.10)	
Median	2.0	3.0	3.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	2.0 (1.20)	2.3 (1.06)	2.4 (1.09)	2.1 (1.20)	
Median	2.0	3.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	-0.23 (0.377)	-0.50 (0.247)	-0.26 (0.117)	-0.44 (0.085)	
95% CI [2]	-0.99, 0.54	-1.00, -0.00	-0.49, -0.03	-0.61, -0.27	
Difference (95% CI) in CFB [2]		-0.28 (-1.17, 0.61)		-0.18 (-0.46, 0.10)	
p-value [3]		0.532		0.205	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	102	
Mean (StdDev)	2.1 (1.51)	2.2 (1.27)	2.3 (1.04)	2.0 (1.12)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	13	26	51	99	
LS Mean (StdErr) [2]	-0.16 (0.384)	-0.50 (0.251)	-0.45 (0.128)	-0.59 (0.093)	
95% CI [2]	-0.93, 0.62	-1.01, 0.00	-0.71, -0.20	-0.78, -0.41	
Difference (95% CI) in CFB [2]		-0.35 (-1.25, 0.56)		-0.14 (-0.45, 0.17)	
p-value [3]		0.439		0.367	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	1.8 (1.28)	2.5 (1.06)	2.5 (1.06)	1.8 (1.16)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	-0.60 (0.347)	-0.33 (0.224)	-0.26 (0.163)	-0.79 (0.113)	
95% CI [2]	-1.31, 0.10	-0.78, 0.13	-0.58, 0.07	-1.01, -0.56	
Difference (95% CI) in CFB [2]		0.28 (-0.53, 1.09)		-0.53 (-0.91, -0.14)	
p-value [3]		0.491		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	99	
Mean (StdDev)	1.6 (1.01)	2.2 (1.13)	2.4 (1.09)	1.9 (1.15)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	12	25	50	94	
LS Mean (StdErr) [2]	-0.83 (0.422)	-0.60 (0.278)	-0.26 (0.156)	-0.69 (0.116)	
95% CI [2]	-1.69, 0.03	-1.16, -0.03	-0.57, 0.05	-0.92, -0.46	
Difference (95% CI) in CFB [2]		0.23 (-0.75, 1.21)		-0.44 (-0.81, -0.06)	
p-value [3]		0.634		0.024	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	1.4 (1.22)	2.1 (1.19)	2.5 (1.11)	1.7 (1.13)	
Median	1.5	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-0.82 (0.466)	-0.62 (0.299)	-0.12 (0.157)	-0.83 (0.113)	
95% CI [2]	-1.76, 0.13	-1.23, -0.01	-0.43, 0.19	-1.05, -0.60	
Difference (95% CI) in CFB [2]		0.20 (-0.89, 1.28)		-0.71 (-1.09, -0.33)	
p-value [3]		0.715		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	1.9 (1.32)	2.1 (1.05)	2.3 (1.21)	1.7 (1.16)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	-0.26 (0.402)	-0.58 (0.260)	-0.32 (0.162)	-0.84 (0.116)	
95% CI [2]	-1.08, 0.56	-1.11, -0.05	-0.64, -0.00	-1.07, -0.61	
Difference (95% CI) in CFB [2]		-0.32 (-1.26, 0.62)		-0.52 (-0.91, -0.13)	
Hedges'G (95% CI) in CFB		-0.24 (-1.01, 0.48)		-0.45 (-0.81, -0.11)	
p-value [3]		0.487		0.009	
					0.639

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	2.1 (1.12)	2.1 (1.43)	2.2 (1.43)	2.0 (1.28)	
Median	2.0	3.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	1.4 (0.74)	1.7 (1.20)	2.0 (1.39)	1.6 (1.34)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	-0.63 (0.352)	-0.31 (0.230)	-0.12 (0.126)	-0.38 (0.092)	
95% CI [2]	-1.35, 0.08	-0.78, 0.16	-0.37, 0.13	-0.56, -0.20	
Difference (95% CI) in CFB [2]		0.32 (-0.51, 1.15)		-0.26 (-0.57, 0.04)	
p-value [3]		0.439		0.090	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	51	102	
Mean (StdDev)	1.2 (1.01)	1.7 (1.13)	1.8 (1.31)	1.4 (1.26)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	13	26	50	99	
LS Mean (StdErr) [2]	-0.77 (0.302)	-0.44 (0.197)	-0.37 (0.145)	-0.53 (0.104)	
95% CI [2]	-1.38, -0.16	-0.84, -0.04	-0.65, -0.08	-0.74, -0.33	
Difference (95% CI) in CFB [2]		0.33 (-0.39, 1.04)		-0.16 (-0.51, 0.18)	
p-value [3]		0.361		0.350	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	0.8 (0.99)	1.8 (1.20)	2.0 (1.35)	1.4 (1.31)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	-1.22 (0.350)	-0.43 (0.226)	-0.26 (0.166)	-0.61 (0.115)	
95% CI [2]	-1.93, -0.51	-0.89, 0.03	-0.59, 0.07	-0.84, -0.38	
Difference (95% CI) in CFB [2]		0.79 (-0.03, 1.61)		-0.34 (-0.74, 0.05)	
p-value [3]		0.058		0.085	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	99	
Mean (StdDev)	0.9 (0.73)	1.5 (1.14)	1.9 (1.40)	1.2 (1.26)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C5D1 CFB					
n	12	25	50	94	
LS Mean (StdErr) [2]	-1.00 (0.373)	-0.60 (0.246)	-0.32 (0.168)	-0.79 (0.126)	
95% CI [2]	-1.76, -0.24	-1.10, -0.10	-0.65, 0.02	-1.04, -0.54	
Difference (95% CI) in CFB [2]		0.39 (-0.47, 1.26)		-0.47 (-0.88, -0.06)	
p-value [3]		0.363		0.024	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	1.1 (0.83)	1.5 (1.12)	2.1 (1.46)	1.2 (1.23)	
Median	1.0	2.0	2.5	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-1.06 (0.408)	-0.68 (0.262)	-0.02 (0.163)	-0.75 (0.117)	
95% CI [2]	-1.89, -0.23	-1.21, -0.14	-0.34, 0.30	-0.99, -0.52	
Difference (95% CI) in CFB [2]		0.39 (-0.56, 1.33)		-0.74 (-1.13, -0.34)	
p-value [3]		0.413		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	1.2 (0.73)	1.4 (1.19)	1.9 (1.46)	1.2 (1.34)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	-0.70 (0.324)	-0.61 (0.210)	-0.31 (0.162)	-0.76 (0.117)	
95% CI [2]	-1.36, -0.04	-1.04, -0.18	-0.63, 0.01	-1.00, -0.53	
Difference (95% CI) in CFB [2]		0.09 (-0.66, 0.85)		-0.46 (-0.85, -0.07)	
Hedges'G (95% CI) in CFB		0.09 (-0.65, 0.83)		-0.40 (-0.75, -0.05)	
p-value [3]		0.805		0.021	
					0.293

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	55	108	
Mean (StdDev)	2.1 (0.86)	2.6 (1.37)	2.5 (1.07)	2.4 (1.05)	
Median	2.0	3.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	1.6 (0.83)	1.8 (1.09)	1.9 (1.14)	1.8 (1.17)	
Median	1.0	2.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	26	53	106	
LS Mean (StdErr) [2]	-0.35 (0.392)	-0.72 (0.256)	-0.46 (0.138)	-0.60 (0.100)	
95% CI [2]	-1.14, 0.44	-1.24, -0.20	-0.73, -0.19	-0.80, -0.41	
Difference (95% CI) in CFB [2]		-0.37 (-1.30, 0.55)		-0.14 (-0.47, 0.19)	
p-value [3]		0.418		0.396	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	101	
Mean (StdDev)	1.7 (1.11)	1.8 (1.01)	2.0 (1.12)	1.6 (1.08)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	13	26	51	98	
LS Mean (StdErr) [2]	-0.40 (0.321)	-0.68 (0.210)	-0.46 (0.160)	-0.81 (0.117)	
95% CI [2]	-1.05, 0.26	-1.10, -0.25	-0.78, -0.15	-1.04, -0.58	
Difference (95% CI) in CFB [2]		-0.28 (-1.04, 0.48)		-0.34 (-0.73, 0.04)	
p-value [3]		0.455		0.078	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	1.5 (0.88)	2.0 (1.08)	2.0 (1.17)	1.5 (1.15)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	11	24	46	101	
LS Mean (StdErr) [2]	-0.66 (0.340)	-0.64 (0.220)	-0.48 (0.168)	-0.91 (0.116)	
95% CI [2]	-1.36, 0.03	-1.09, -0.19	-0.81, -0.15	-1.14, -0.68	
Difference (95% CI) in CFB [2]		0.02 (-0.77, 0.81)		-0.42 (-0.82, -0.03)	
p-value [3]		0.955		0.037	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	99	
Mean (StdDev)	1.1 (0.66)	1.7 (1.04)	1.9 (1.24)	1.4 (1.18)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C5D1 CFB					
n	12	25	50	94	
LS Mean (StdErr) [2]	-1.00 (0.351)	-0.88 (0.231)	-0.52 (0.174)	-0.98 (0.130)	
95% CI [2]	-1.72, -0.29	-1.35, -0.41	-0.87, -0.18	-1.24, -0.73	
Difference (95% CI) in CFB [2]		0.12 (-0.69, 0.94)		-0.46 (-0.88, -0.04)	
p-value [3]		0.763		0.033	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	1.3 (0.73)	1.6 (1.15)	2.0 (1.23)	1.4 (1.15)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	26	48	97	
LS Mean (StdErr) [2]	-0.70 (0.364)	-0.99 (0.233)	-0.36 (0.170)	-0.93 (0.123)	
95% CI [2]	-1.44, 0.03	-1.47, -0.52	-0.70, -0.02	-1.17, -0.69	
Difference (95% CI) in CFB [2]		-0.29 (-1.14, 0.55)		-0.57 (-0.98, -0.16)	
p-value [3]		0.490		0.007	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	1.2 (0.69)	1.9 (1.30)	2.0 (1.35)	1.4 (1.24)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C7D1 CFB					
n	11	24	49	97	
LS Mean (StdErr) [2]	-0.73 (0.440)	-0.71 (0.285)	-0.44 (0.192)	-1.03 (0.138)	
95% CI [2]	-1.63, 0.16	-1.29, -0.13	-0.82, -0.06	-1.31, -0.76	
Difference (95% CI) in CFB [2]		0.02 (-1.00, 1.05)		-0.59 (-1.05, -0.13)	
Hedges'G (95% CI) in CFB		0.02 (-0.72, 0.76)		-0.44 (-0.79, -0.09)	
p-value [3]		0.963		0.012	
					0.266

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	13	27	54	108	
Mean (StdDev)	1.7 (1.18)	2.3 (1.29)	2.1 (1.27)	2.1 (1.16)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	1.1 (0.74)	1.9 (1.24)	2.1 (1.25)	1.7 (1.18)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C2D1 CFB					
n	13	26	52	106	
LS Mean (StdErr) [2]	-0.66 (0.315)	-0.36 (0.206)	0.04 (0.143)	-0.37 (0.103)	
95% CI [2]	-1.30, -0.02	-0.77, 0.06	-0.24, 0.32	-0.57, -0.16	
Difference (95% CI) in CFB [2]		0.30 (-0.44, 1.04)		-0.41 (-0.75, -0.06)	
p-value [3]		0.416		0.021	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	102	
Mean (StdDev)	1.4 (1.18)	1.7 (1.23)	1.9 (1.18)	1.5 (1.10)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	13	26	50	99	
LS Mean (StdErr) [2]	-0.22 (0.329)	-0.61 (0.215)	-0.16 (0.139)	-0.56 (0.100)	
95% CI [2]	-0.89, 0.45	-1.05, -0.18	-0.43, 0.12	-0.76, -0.36	
Difference (95% CI) in CFB [2]		-0.39 (-1.17, 0.38)		-0.40 (-0.74, -0.07)	
p-value [3]		0.313		0.018	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	1.0 (0.82)	1.8 (1.17)	1.9 (1.26)	1.5 (1.26)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C4D1 CFB					
n	11	24	45	101	
LS Mean (StdErr) [2]	-0.49 (0.335)	-0.56 (0.217)	-0.15 (0.171)	-0.67 (0.117)	
95% CI [2]	-1.17, 0.20	-1.00, -0.12	-0.48, 0.19	-0.90, -0.44	
Difference (95% CI) in CFB [2]		-0.07 (-0.86, 0.71)		-0.52 (-0.93, -0.12)	
p-value [3]		0.849		0.012	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	99	
Mean (StdDev)	1.1 (0.83)	1.7 (1.15)	1.8 (1.13)	1.4 (1.12)	
Median	1.0	1.5	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	12	25	49	94	
LS Mean (StdErr) [2]	-0.39 (0.349)	-0.55 (0.230)	-0.26 (0.162)	-0.76 (0.120)	
95% CI [2]	-1.10, 0.32	-1.02, -0.09	-0.59, 0.06	-0.99, -0.52	
Difference (95% CI) in CFB [2]		-0.16 (-0.97, 0.65)		-0.49 (-0.89, -0.10)	
p-value [3]		0.687		0.014	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	0.9 (0.66)	1.5 (1.22)	2.0 (1.21)	1.4 (1.19)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C6D1 CFB					
n	12	26	47	97	
LS Mean (StdErr) [2]	-0.77 (0.382)	-0.81 (0.245)	-0.02 (0.164)	-0.77 (0.117)	
95% CI [2]	-1.54, 0.01	-1.31, -0.32	-0.35, 0.30	-1.00, -0.53	
Difference (95% CI) in CFB [2]		-0.05 (-0.93, 0.84)		-0.74 (-1.13, -0.35)	
p-value [3]		0.917		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.6a
Change from Baseline in MC-QoL Individual Item Scores by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	1.0 (0.91)	1.9 (1.17)	1.8 (1.18)	1.4 (1.26)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	11	24	48	97	
LS Mean (StdErr) [2]	-0.32 (0.387)	-0.39 (0.250)	-0.21 (0.174)	-0.74 (0.125)	
95% CI [2]	-1.11, 0.47	-0.90, 0.12	-0.55, 0.14	-0.98, -0.49	
Difference (95% CI) in CFB [2]		-0.07 (-0.98, 0.83)		-0.53 (-0.95, -0.11)	
Hedges'G (95% CI) in CFB		-0.06 (-0.80, 0.68)		-0.43 (-0.79, -0.09)	
p-value [3]		0.869		0.013	
					0.435

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-tryp-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	2.8 (1.11)	2.3 (1.13)	2.0 (1.83)	2.3 (1.16)	
Median	3.0	2.0	2.0	2.5	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	2.3 (1.02)	1.6 (0.93)	2.0 (1.63)	1.9 (1.27)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	-0.41 (0.144)	-0.65 (0.110)	0.85 (0.959)	0.41 (0.730)	
95% CI [2]	-0.70, -0.13	-0.87, -0.43	-1.32, 3.02	-1.24, 2.06	
Difference (95% CI) in CFB [2]		-0.24 (-0.56, 0.08)		-0.43 (-2.25, 1.38)	
p-value [3]		0.136		0.601	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	119	4	9	
Mean (StdDev)	2.1 (1.13)	1.5 (0.92)	1.3 (0.96)	2.0 (1.41)	
Median	2.0	1.0	1.5	2.0	
Min, Max	0, 4	0, 4	0, 2	0, 4	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-0.57 (0.163)	-0.75 (0.124)	0.04 (0.841)	0.49 (0.640)	
95% CI [2]	-0.90, -0.25	-0.99, -0.51	-1.86, 1.95	-0.96, 1.94	
Difference (95% CI) in CFB [2]		-0.17 (-0.53, 0.18)		0.45 (-1.15, 2.04)	
p-value [3]		0.339		0.542	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	2.2 (1.06)	1.4 (1.01)	2.0 (1.63)	1.9 (0.99)	
Median	2.0	1.0	2.0	1.5	
Min, Max	0, 4	0, 4	0, 4	1, 3	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-0.50 (0.178)	-0.95 (0.132)	0.35 (0.994)	0.04 (0.761)	
95% CI [2]	-0.85, -0.15	-1.21, -0.69	-1.86, 2.57	-1.66, 1.73	
Difference (95% CI) in CFB [2]		-0.44 (-0.83, -0.06)		-0.31 (-2.15, 1.52)	
p-value [3]		0.024		0.711	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	114	4	10	
Mean (StdDev)	2.3 (1.19)	1.3 (1.00)	1.5 (1.00)	1.4 (0.97)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 2	0, 3	
C5D1 CFB					
n	58	108	4	10	
LS Mean (StdErr) [2]	-0.39 (0.180)	-0.91 (0.139)	0.22 (0.721)	-0.06 (0.552)	
95% CI [2]	-0.75, -0.04	-1.18, -0.63	-1.38, 1.83	-1.28, 1.17	
Difference (95% CI) in CFB [2]		-0.51 (-0.91, -0.12)		-0.28 (-1.61, 1.06)	
p-value [3]		0.011		0.652	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	2.2 (1.23)	1.4 (1.04)	1.5 (1.00)	2.0 (1.05)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 2	0, 3	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-0.51 (0.177)	-0.82 (0.132)	-0.22 (0.721)	0.06 (0.552)	
95% CI [2]	-0.86, -0.16	-1.08, -0.56	-1.83, 1.38	-1.17, 1.28	
Difference (95% CI) in CFB [2]		-0.31 (-0.70, 0.07)		0.28 (-1.06, 1.61)	
p-value [3]		0.113		0.652	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	2.3 (1.17)	1.3 (1.00)	1.5 (1.00)	1.7 (1.06)	
Median	2.0	1.0	2.0	1.5	
Min, Max	0, 4	0, 4	0, 2	0, 3	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-0.35 (0.167)	-0.86 (0.126)	0.00 (0.803)	-0.00 (0.615)	
95% CI [2]	-0.68, -0.03	-1.11, -0.61	-1.79, 1.79	-1.37, 1.37	
Difference (95% CI) in CFB [2]		-0.51 (-0.87, -0.14)		0.00 (-1.49, 1.49)	
Hedges'G (95% CI) in CFB		-0.39 (-0.72, -0.07)		-0.00 (-1.29, 1.29)	
p-value [3]		0.006		>0.999	
					0.421

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	2.5 (1.15)	2.0 (1.14)	2.0 (1.41)	2.4 (1.17)	
Median	2.5	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	2.2 (1.16)	1.4 (0.96)	1.8 (1.26)	1.9 (1.17)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	-0.18 (0.157)	-0.55 (0.120)	-0.59 (0.938)	-0.73 (0.715)	
95% CI [2]	-0.49, 0.12	-0.78, -0.31	-2.71, 1.54	-2.34, 0.89	
Difference (95% CI) in CFB [2]		-0.36 (-0.71, -0.02)		-0.14 (-1.92, 1.63)	
p-value [3]		0.039		0.861	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	119	4	9	
Mean (StdDev)	2.1 (1.22)	1.4 (0.99)	2.0 (1.63)	2.0 (1.00)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-0.36 (0.172)	-0.62 (0.131)	-0.85 (0.859)	-0.91 (0.654)	
95% CI [2]	-0.70, -0.02	-0.88, -0.36	-2.79, 1.10	-2.39, 0.57	
Difference (95% CI) in CFB [2]		-0.26 (-0.64, 0.12)		-0.07 (-1.69, 1.56)	
p-value [3]		0.174		0.930	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	2.1 (1.11)	1.2 (1.01)	2.0 (1.41)	1.7 (1.06)	
Median	2.0	1.0	2.5	1.5	
Min, Max	0, 4	0, 4	0, 3	0, 3	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-0.19 (0.173)	-0.69 (0.129)	-0.69 (0.929)	-1.20 (0.711)	
95% CI [2]	-0.53, 0.16	-0.94, -0.43	-2.76, 1.38	-2.79, 0.38	
Difference (95% CI) in CFB [2]		-0.50 (-0.87, -0.12)		-0.52 (-2.24, 1.20)	
p-value [3]		0.010		0.517	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	114	4	10	
Mean (StdDev)	2.1 (1.29)	1.3 (0.98)	1.5 (1.29)	1.6 (1.17)	
Median	2.0	1.0	1.5	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C5D1 CFB					
n	58	108	4	10	
LS Mean (StdErr) [2]	-0.24 (0.176)	-0.60 (0.136)	-0.54 (1.035)	-0.74 (0.793)	
95% CI [2]	-0.58, 0.11	-0.87, -0.33	-2.84, 1.77	-2.51, 1.03	
Difference (95% CI) in CFB [2]		-0.36 (-0.75, 0.03)		-0.20 (-2.12, 1.71)	
p-value [3]		0.069		0.818	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	2.1 (1.19)	1.3 (1.02)	1.8 (1.26)	2.0 (1.49)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-0.13 (0.173)	-0.60 (0.129)	-1.13 (1.044)	-1.09 (0.799)	
95% CI [2]	-0.47, 0.21	-0.86, -0.35	-3.46, 1.20	-2.87, 0.69	
Difference (95% CI) in CFB [2]		-0.47 (-0.85, -0.09)		0.04 (-1.89, 1.97)	
p-value [3]		0.015		0.967	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	2.1 (1.23)	1.4 (1.08)	1.8 (1.26)	1.7 (1.34)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-0.13 (0.179)	-0.54 (0.135)	-0.39 (1.197)	-0.78 (0.916)	
95% CI [2]	-0.48, 0.23	-0.81, -0.28	-3.06, 2.28	-2.82, 1.26	
Difference (95% CI) in CFB [2]		-0.41 (-0.80, -0.02)		-0.39 (-2.60, 1.83)	
Hedges'G (95% CI) in CFB		-0.30 (-0.62, 0.03)		-0.13 (-1.45, 1.13)	
p-value [3]		0.038		0.704	
					0.947

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	2.3 (1.07)	2.3 (1.09)	1.0 (1.41)	2.2 (1.23)	
Median	2.0	2.0	0.5	2.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	2.1 (1.06)	1.8 (1.09)	1.3 (1.26)	1.7 (0.71)	
Median	2.0	2.0	1.0	2.0	
Min, Max	0, 4	0, 4	0, 3	1, 3	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	-0.19 (0.141)	-0.37 (0.108)	0.02 (0.521)	-0.38 (0.397)	
95% CI [2]	-0.47, 0.09	-0.58, -0.16	-1.16, 1.20	-1.28, 0.52	
Difference (95% CI) in CFB [2]		-0.18 (-0.49, 0.13)		-0.40 (-1.39, 0.58)	
p-value [3]		0.264		0.380	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	119	4	9	
Mean (StdDev)	2.0 (0.98)	1.7 (1.10)	1.5 (1.29)	1.9 (1.17)	
Median	2.0	2.0	1.5	1.0	
Min, Max	0, 4	0, 4	0, 3	1, 4	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-0.22 (0.161)	-0.49 (0.122)	1.24 (0.670)	0.57 (0.510)	
95% CI [2]	-0.53, 0.10	-0.73, -0.25	-0.28, 2.75	-0.59, 1.72	
Difference (95% CI) in CFB [2]		-0.27 (-0.63, 0.08)		-0.67 (-1.94, 0.59)	
p-value [3]		0.134		0.260	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	2.1 (1.05)	1.6 (1.00)	1.3 (1.89)	2.2 (1.23)	
Median	2.0	2.0	0.5	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-0.21 (0.169)	-0.62 (0.125)	0.96 (0.834)	0.76 (0.639)	
95% CI [2]	-0.54, 0.13	-0.87, -0.37	-0.90, 2.82	-0.66, 2.18	
Difference (95% CI) in CFB [2]		-0.41 (-0.78, -0.04)		-0.20 (-1.75, 1.34)	
p-value [3]		0.029		0.775	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	114	4	10	
Mean (StdDev)	1.9 (1.19)	1.7 (1.00)	2.5 (1.91)	2.2 (1.40)	
Median	2.0	2.0	3.0	2.5	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	58	108	4	10	
LS Mean (StdErr) [2]	-0.32 (0.165)	-0.53 (0.128)	0.57 (1.006)	-0.52 (0.770)	
95% CI [2]	-0.65, 0.00	-0.78, -0.28	-1.67, 2.82	-2.24, 1.20	
Difference (95% CI) in CFB [2]		-0.21 (-0.57, 0.16)		-1.09 (-2.95, 0.77)	
p-value [3]		0.262		0.220	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	1.9 (1.16)	1.6 (1.06)	2.0 (1.41)	2.2 (1.48)	
Median	2.0	1.0	2.5	2.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-0.33 (0.166)	-0.62 (0.125)	2.15 (0.783)	0.96 (0.599)	
95% CI [2]	-0.66, 0.00	-0.87, -0.37	0.40, 3.89	-0.37, 2.30	
Difference (95% CI) in CFB [2]		-0.29 (-0.66, 0.08)		-1.19 (-2.63, 0.26)	
p-value [3]		0.120		0.098	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	1.9 (1.12)	1.6 (1.08)	1.8 (1.50)	2.0 (1.25)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-0.32 (0.187)	-0.59 (0.141)	0.87 (0.667)	-0.09 (0.511)	
95% CI [2]	-0.69, 0.05	-0.87, -0.32	-0.62, 2.36	-1.23, 1.05	
Difference (95% CI) in CFB [2]		-0.28 (-0.68, 0.13)		-0.96 (-2.20, 0.27)	
Hedges'G (95% CI) in CFB		-0.19 (-0.52, 0.13)		-0.58 (-2.02, 0.62)	
p-value [3]		0.179		0.113	
					0.415

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	2.0 (1.21)	2.1 (1.21)	2.8 (1.26)	2.2 (1.48)	
Median	2.0	2.0	3.0	2.5	
Min, Max	0, 4	0, 4	1, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	127	4	9	
Mean (StdDev)	1.7 (1.18)	1.4 (1.06)	2.0 (1.41)	2.1 (1.54)	
Median	2.0	1.0	1.5	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C2D1 CFB					
n	62	122	4	9	
LS Mean (StdErr) [2]	-0.27 (0.159)	-0.60 (0.123)	-0.59 (0.938)	-0.23 (0.715)	
95% CI [2]	-0.58, 0.05	-0.84, -0.36	-2.71, 1.54	-1.84, 1.39	
Difference (95% CI) in CFB [2]		-0.33 (-0.68, 0.02)		0.36 (-1.42, 2.13)	
p-value [3]		0.061		0.659	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	119	4	9	
Mean (StdDev)	1.7 (1.30)	1.4 (1.10)	2.8 (0.96)	1.9 (1.54)	
Median	1.0	1.0	2.5	2.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-0.23 (0.175)	-0.60 (0.133)	0.17 (1.051)	-0.54 (0.801)	
95% CI [2]	-0.58, 0.11	-0.86, -0.34	-2.20, 2.55	-2.35, 1.27	
Difference (95% CI) in CFB [2]		-0.37 (-0.76, 0.02)		-0.72 (-2.71, 1.27)	
p-value [3]		0.060		0.436	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	1.7 (1.21)	1.4 (1.16)	2.8 (0.96)	1.4 (1.43)	
Median	2.0	1.0	2.5	1.5	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-0.38 (0.177)	-0.63 (0.131)	0.43 (0.951)	-0.48 (0.728)	
95% CI [2]	-0.73, -0.03	-0.89, -0.37	-1.69, 2.55	-2.10, 1.14	
Difference (95% CI) in CFB [2]		-0.25 (-0.64, 0.13)		-0.91 (-2.67, 0.85)	
p-value [3]		0.197		0.277	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	114	4	10	
Mean (StdDev)	1.8 (1.13)	1.4 (1.14)	2.3 (0.50)	1.4 (1.35)	
Median	2.0	1.0	2.0	1.5	
Min, Max	0, 4	0, 4	2, 3	0, 3	
C5D1 CFB					
n	58	108	4	10	
LS Mean (StdErr) [2]	-0.14 (0.180)	-0.71 (0.139)	-0.13 (0.845)	-0.59 (0.647)	
95% CI [2]	-0.50, 0.21	-0.98, -0.43	-2.01, 1.75	-2.03, 0.85	
Difference (95% CI) in CFB [2]		-0.57 (-0.96, -0.17)		-0.46 (-2.03, 1.10)	
p-value [3]		0.006		0.524	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	1.7 (1.17)	1.3 (1.11)	2.0 (1.63)	1.0 (1.25)	
Median	2.0	1.0	2.0	0.5	
Min, Max	0, 4	0, 4	0, 4	0, 3	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-0.16 (0.175)	-0.64 (0.131)	-0.11 (1.054)	-0.72 (0.807)	
95% CI [2]	-0.51, 0.18	-0.89, -0.38	-2.46, 2.24	-2.52, 1.08	
Difference (95% CI) in CFB [2]		-0.47 (-0.86, -0.09)		-0.61 (-2.56, 1.34)	
p-value [3]		0.017		0.501	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	1.7 (1.10)	1.4 (1.19)	1.8 (1.26)	1.4 (1.51)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-0.07 (0.179)	-0.54 (0.135)	-0.57 (0.951)	-0.48 (0.728)	
95% CI [2]	-0.42, 0.28	-0.80, -0.27	-2.69, 1.55	-2.10, 1.14	
Difference (95% CI) in CFB [2]		-0.47 (-0.86, -0.08)		0.09 (-1.67, 1.85)	
Hedges'G (95% CI) in CFB		-0.33 (-0.66, -0.01)		0.04 (-1.24, 1.34)	
p-value [3]		0.019		0.909	
					0.337

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	3.1 (0.91)	3.2 (0.93)	3.8 (0.50)	3.2 (0.92)	
Median	3.0	3.0	4.0	3.0	
Min, Max	1, 4	1, 4	3, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	2.8 (0.96)	2.6 (1.09)	3.3 (0.50)	2.9 (0.93)	
Median	3.0	3.0	3.0	3.0	
Min, Max	1, 4	0, 4	3, 4	1, 4	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	-0.32 (0.134)	-0.52 (0.103)	-0.98 (0.589)	-0.63 (0.448)	
95% CI [2]	-0.59, -0.06	-0.72, -0.32	-2.31, 0.35	-1.64, 0.38	
Difference (95% CI) in CFB [2]		-0.20 (-0.49, 0.10)		0.35 (-0.77, 1.46)	
p-value [3]		0.191		0.498	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	119	4	9	
Mean (StdDev)	2.6 (1.08)	2.4 (1.09)	3.3 (0.96)	3.0 (1.00)	
Median	3.0	2.0	3.5	3.0	
Min, Max	0, 4	0, 4	2, 4	1, 4	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-0.44 (0.154)	-0.73 (0.117)	-0.54 (0.735)	-0.24 (0.560)	
95% CI [2]	-0.75, -0.14	-0.96, -0.50	-2.21, 1.12	-1.51, 1.03	
Difference (95% CI) in CFB [2]		-0.29 (-0.63, 0.05)		0.30 (-1.09, 1.70)	
p-value [3]		0.093		0.633	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	2.7 (1.13)	2.4 (1.13)	3.5 (0.58)	3.0 (0.94)	
Median	3.0	2.0	3.5	3.0	
Min, Max	1, 4	0, 4	3, 4	1, 4	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-0.42 (0.166)	-0.68 (0.123)	-0.76 (0.961)	-0.69 (0.736)	
95% CI [2]	-0.75, -0.09	-0.93, -0.44	-2.90, 1.38	-2.32, 0.95	
Difference (95% CI) in CFB [2]		-0.26 (-0.62, 0.10)		0.07 (-1.70, 1.85)	
p-value [3]		0.150		0.928	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	114	4	10	
Mean (StdDev)	2.7 (1.20)	2.3 (1.13)	3.3 (0.96)	2.9 (0.99)	
Median	3.0	2.0	3.5	3.0	
Min, Max	0, 4	0, 4	2, 4	1, 4	
C5D1 CFB					
n	58	108	4	10	
LS Mean (StdErr) [2]	-0.43 (0.165)	-0.79 (0.128)	-1.07 (0.831)	-0.98 (0.636)	
95% CI [2]	-0.75, -0.10	-1.04, -0.54	-2.93, 0.78	-2.40, 0.44	
Difference (95% CI) in CFB [2]		-0.36 (-0.73, 0.00)		0.09 (-1.44, 1.63)	
p-value [3]		0.052		0.896	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	2.5 (1.08)	2.2 (1.16)	3.8 (0.50)	3.0 (0.94)	
Median	2.0	2.0	4.0	3.0	
Min, Max	0, 4	0, 4	3, 4	2, 4	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-0.61 (0.167)	-0.86 (0.125)	-1.06 (0.857)	-1.11 (0.656)	
95% CI [2]	-0.94, -0.28	-1.11, -0.62	-2.96, 0.85	-2.57, 0.35	
Difference (95% CI) in CFB [2]		-0.25 (-0.62, 0.12)		-0.06 (-1.64, 1.53)	
p-value [3]		0.181		0.939	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	2.5 (1.08)	2.3 (1.07)	3.5 (0.58)	3.0 (0.82)	
Median	3.0	2.0	3.5	3.0	
Min, Max	0, 4	0, 4	3, 4	2, 4	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-0.56 (0.167)	-0.78 (0.126)	-0.76 (0.841)	-0.69 (0.644)	
95% CI [2]	-0.89, -0.23	-1.02, -0.53	-2.63, 1.12	-2.12, 0.75	
Difference (95% CI) in CFB [2]		-0.22 (-0.58, 0.15)		0.07 (-1.48, 1.63)	
Hedges'G (95% CI) in CFB		-0.17 (-0.49, 0.16)		0.04 (-1.25, 1.33)	
p-value [3]		0.238		0.918	
					0.664

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	2.1 (1.11)	2.1 (1.13)	2.3 (1.26)	2.1 (1.20)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	1.9 (1.07)	1.8 (1.02)	2.0 (1.41)	1.7 (1.22)	
Median	2.0	2.0	1.5	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 3	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	-0.15 (0.135)	-0.30 (0.104)	-0.11 (0.367)	-0.10 (0.279)	
95% CI [2]	-0.42, 0.12	-0.51, -0.10	-0.94, 0.72	-0.73, 0.53	
Difference (95% CI) in CFB [2]		-0.15 (-0.45, 0.14)		0.01 (-0.68, 0.71)	
p-value [3]		0.312		0.973	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	119	4	9	
Mean (StdDev)	1.9 (1.08)	1.6 (0.98)	1.8 (1.50)	1.2 (1.30)	
Median	2.0	2.0	1.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 3	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-0.24 (0.157)	-0.49 (0.119)	-0.70 (0.644)	-0.83 (0.491)	
95% CI [2]	-0.55, 0.07	-0.73, -0.26	-2.15, 0.76	-1.94, 0.28	
Difference (95% CI) in CFB [2]		-0.25 (-0.60, 0.10)		-0.13 (-1.35, 1.09)	
p-value [3]		0.155		0.814	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	1.8 (1.16)	1.7 (1.11)	2.5 (1.73)	1.8 (1.55)	
Median	2.0	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-0.27 (0.169)	-0.38 (0.125)	-0.13 (0.744)	-0.59 (0.569)	
95% CI [2]	-0.61, 0.06	-0.63, -0.13	-1.79, 1.53	-1.86, 0.68	
Difference (95% CI) in CFB [2]		-0.11 (-0.47, 0.26)		-0.46 (-1.84, 0.91)	
p-value [3]		0.566		0.471	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	114	4	10	
Mean (StdDev)	1.9 (1.24)	1.6 (1.08)	2.0 (1.41)	1.9 (1.73)	
Median	2.0	2.0	1.5	1.5	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C5D1 CFB					
n	58	108	4	10	
LS Mean (StdErr) [2]	-0.27 (0.157)	-0.39 (0.122)	0.33 (0.568)	0.17 (0.435)	
95% CI [2]	-0.58, 0.04	-0.63, -0.15	-0.93, 1.60	-0.80, 1.14	
Difference (95% CI) in CFB [2]		-0.12 (-0.47, 0.23)		-0.17 (-1.22, 0.88)	
p-value [3]		0.502		0.731	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	1.8 (1.06)	1.5 (1.06)	3.0 (0.82)	1.7 (1.83)	
Median	2.0	1.0	3.0	1.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-0.36 (0.151)	-0.45 (0.113)	1.48 (0.759)	0.13 (0.581)	
95% CI [2]	-0.66, -0.06	-0.68, -0.23	-0.21, 3.17	-1.17, 1.43	
Difference (95% CI) in CFB [2]		-0.09 (-0.43, 0.24)		-1.35 (-2.76, 0.05)	
p-value [3]		0.576		0.058	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	1.7 (1.12)	1.6 (1.09)	2.0 (0.82)	1.6 (1.35)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-0.33 (0.167)	-0.39 (0.126)	-0.59 (0.493)	-0.85 (0.377)	
95% CI [2]	-0.66, 0.00	-0.64, -0.15	-1.69, 0.51	-1.69, -0.01	
Difference (95% CI) in CFB [2]		-0.07 (-0.43, 0.30)		-0.26 (-1.17, 0.65)	
Hedges'G (95% CI) in CFB		-0.05 (-0.37, 0.27)		-0.21 (-1.55, 1.04)	
p-value [3]		0.720		0.540	
					0.800

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	2.7 (1.16)	2.7 (1.24)	3.3 (0.96)	3.3 (0.67)	
Median	3.0	3.0	3.5	3.0	
Min, Max	0, 4	0, 4	2, 4	2, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	127	4	9	
Mean (StdDev)	2.3 (1.08)	2.1 (1.14)	2.8 (0.96)	2.9 (0.93)	
Median	2.0	2.0	2.5	3.0	
Min, Max	0, 4	0, 4	2, 4	1, 4	
C2D1 CFB					
n	62	122	4	9	
LS Mean (StdErr) [2]	-0.27 (0.133)	-0.42 (0.103)	-0.89 (0.387)	-0.65 (0.295)	
95% CI [2]	-0.53, -0.01	-0.63, -0.22	-1.77, -0.02	-1.32, 0.01	
Difference (95% CI) in CFB [2]		-0.16 (-0.45, 0.14)		0.24 (-0.49, 0.97)	
p-value [3]		0.297		0.479	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	119	4	9	
Mean (StdDev)	2.2 (1.11)	2.0 (1.22)	2.8 (1.26)	3.2 (0.67)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	1, 4	2, 4	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-0.48 (0.163)	-0.63 (0.124)	-1.02 (0.324)	-0.37 (0.247)	
95% CI [2]	-0.80, -0.16	-0.88, -0.39	-1.75, -0.29	-0.93, 0.19	
Difference (95% CI) in CFB [2]		-0.16 (-0.52, 0.20)		0.65 (0.04, 1.27)	
p-value [3]		0.392		0.040	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	2.3 (1.08)	2.0 (1.18)	3.3 (1.50)	3.4 (0.84)	
Median	2.0	2.0	4.0	4.0	
Min, Max	0, 4	0, 4	1, 4	2, 4	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-0.30 (0.180)	-0.59 (0.133)	-0.02 (0.602)	0.13 (0.461)	
95% CI [2]	-0.65, 0.06	-0.86, -0.33	-1.36, 1.32	-0.90, 1.16	
Difference (95% CI) in CFB [2]		-0.30 (-0.69, 0.09)		0.15 (-0.97, 1.26)	
p-value [3]		0.134		0.773	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	114	4	10	
Mean (StdDev)	2.4 (1.09)	2.0 (1.19)	3.0 (1.41)	3.3 (1.06)	
Median	3.0	2.0	3.5	4.0	
Min, Max	0, 4	0, 4	1, 4	1, 4	
C5D1 CFB					
n	58	108	4	10	
LS Mean (StdErr) [2]	-0.25 (0.160)	-0.58 (0.124)	-0.39 (0.598)	-0.28 (0.458)	
95% CI [2]	-0.56, 0.07	-0.82, -0.33	-1.72, 0.94	-1.30, 0.74	
Difference (95% CI) in CFB [2]		-0.33 (-0.68, 0.02)		0.11 (-1.00, 1.22)	
p-value [3]		0.068		0.828	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	2.4 (1.18)	2.0 (1.19)	3.3 (0.96)	3.0 (1.05)	
Median	2.0	2.0	3.5	3.0	
Min, Max	0, 4	0, 4	2, 4	1, 4	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-0.24 (0.171)	-0.58 (0.128)	-0.41 (0.715)	-0.65 (0.547)	
95% CI [2]	-0.57, 0.10	-0.84, -0.33	-2.00, 1.19	-1.87, 0.57	
Difference (95% CI) in CFB [2]		-0.35 (-0.72, 0.03)		-0.24 (-1.56, 1.08)	
p-value [3]		0.073		0.694	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	2.2 (1.15)	2.0 (1.15)	2.8 (1.50)	3.2 (1.14)	
Median	2.0	2.0	3.0	4.0	
Min, Max	0, 4	0, 4	1, 4	1, 4	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-0.34 (0.163)	-0.49 (0.123)	-0.43 (0.727)	-0.02 (0.557)	
95% CI [2]	-0.66, -0.01	-0.73, -0.25	-2.05, 1.19	-1.26, 1.22	
Difference (95% CI) in CFB [2]		-0.15 (-0.51, 0.20)		0.41 (-0.94, 1.75)	
Hedges'G (95% CI) in CFB		-0.12 (-0.45, 0.20)		0.23 (-1.02, 1.57)	
p-value [3]		0.396		0.515	
					0.317

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	2.2 (1.12)	2.6 (1.07)	3.3 (0.96)	2.4 (1.51)	
Median	2.0	3.0	3.5	3.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	64	128	4	9	
Mean (StdDev)	2.0 (1.21)	2.1 (1.12)	2.8 (0.50)	1.3 (1.12)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	2, 3	0, 3	
C2D1 CFB					
n	61	123	4	9	
LS Mean (StdErr) [2]	-0.06 (0.120)	-0.46 (0.092)	-1.76 (0.996)	-1.93 (0.759)	
95% CI [2]	-0.30, 0.18	-0.64, -0.28	-4.01, 0.49	-3.65, -0.22	
Difference (95% CI) in CFB [2]		-0.40 (-0.67, -0.14)		-0.17 (-2.06, 1.71)	
p-value [3]		0.003		0.839	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	119	4	9	
Mean (StdDev)	2.0 (1.23)	1.9 (1.15)	2.3 (0.96)	1.6 (0.88)	
Median	2.0	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	1, 3	0, 3	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-0.08 (0.120)	-0.64 (0.091)	-1.26 (1.026)	-0.93 (0.781)	
95% CI [2]	-0.31, 0.16	-0.82, -0.46	-3.58, 1.06	-2.70, 0.83	
Difference (95% CI) in CFB [2]		-0.56 (-0.83, -0.30)		0.33 (-1.62, 2.27)	
p-value [3]		<0.0001		0.713	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	1.9 (1.23)	1.9 (1.16)	2.5 (0.58)	2.0 (1.15)	
Median	2.0	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	2, 3	0, 4	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-0.14 (0.141)	-0.60 (0.105)	-1.11 (1.054)	-0.72 (0.807)	
95% CI [2]	-0.42, 0.14	-0.81, -0.40	-3.46, 1.24	-2.52, 1.08	
Difference (95% CI) in CFB [2]		-0.47 (-0.77, -0.16)		0.39 (-1.56, 2.34)	
p-value [3]		0.003		0.666	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	114	4	10	
Mean (StdDev)	2.0 (1.25)	1.8 (1.12)	2.5 (1.00)	2.1 (1.37)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C5D1 CFB					
n	58	108	4	10	
LS Mean (StdErr) [2]	-0.09 (0.142)	-0.66 (0.110)	-0.72 (1.103)	-0.44 (0.845)	
95% CI [2]	-0.37, 0.19	-0.88, -0.45	-3.18, 1.74	-2.33, 1.44	
Difference (95% CI) in CFB [2]		-0.57 (-0.88, -0.26)		0.28 (-1.76, 2.32)	
p-value [3]		<0.001		0.768	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	1.8 (1.21)	1.7 (1.21)	3.3 (0.50)	1.9 (1.29)	
Median	2.0	2.0	3.0	1.5	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-0.29 (0.149)	-0.77 (0.111)	0.26 (1.092)	-0.31 (0.836)	
95% CI [2]	-0.59, 0.00	-0.99, -0.55	-2.17, 2.69	-2.18, 1.55	
Difference (95% CI) in CFB [2]		-0.48 (-0.81, -0.15)		-0.57 (-2.59, 1.45)	
p-value [3]		0.004		0.541	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	1.9 (1.19)	1.7 (1.21)	3.0 (0.82)	1.8 (1.23)	
Median	2.0	2.0	3.0	1.5	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-0.12 (0.144)	-0.77 (0.108)	-0.57 (1.266)	-0.98 (0.969)	
95% CI [2]	-0.40, 0.17	-0.98, -0.55	-3.40, 2.25	-3.14, 1.18	
Difference (95% CI) in CFB [2]		-0.65 (-0.96, -0.34)		-0.41 (-2.75, 1.94)	
Hedges'G (95% CI) in CFB		-0.58 (-0.91, -0.26)		-0.13 (-1.45, 1.13)	
p-value [3]		<0.0001		0.707	
					0.606

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	2.0 (1.37)	2.1 (1.41)	2.5 (1.73)	1.7 (1.57)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	1.6 (1.33)	1.6 (1.34)	2.0 (2.31)	1.8 (1.56)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	-0.24 (0.184)	-0.46 (0.141)	-1.85 (1.479)	-0.91 (1.126)	
95% CI [2]	-0.60, 0.13	-0.74, -0.18	-5.19, 1.50	-3.46, 1.63	
Difference (95% CI) in CFB [2]		-0.22 (-0.62, 0.18)		0.93 (-1.86, 3.73)	
p-value [3]		0.282		0.469	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	118	4	9	
Mean (StdDev)	1.7 (1.33)	1.6 (1.32)	2.8 (0.50)	1.0 (1.50)	
Median	1.0	1.0	3.0	0.0	
Min, Max	0, 4	0, 4	2, 3	0, 4	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-0.20 (0.194)	-0.45 (0.147)	-1.37 (1.461)	-2.03 (1.113)	
95% CI [2]	-0.59, 0.18	-0.74, -0.16	-4.68, 1.94	-4.55, 0.48	
Difference (95% CI) in CFB [2]		-0.24 (-0.67, 0.19)		-0.66 (-3.43, 2.10)	
p-value [3]		0.266		0.601	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	1.7 (1.21)	1.5 (1.27)	3.3 (0.50)	1.8 (1.48)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-0.14 (0.211)	-0.57 (0.157)	-1.07 (1.083)	-1.48 (0.829)	
95% CI [2]	-0.56, 0.27	-0.88, -0.26	-3.49, 1.34	-3.33, 0.37	
Difference (95% CI) in CFB [2]		-0.42 (-0.88, 0.03)		-0.41 (-2.41, 1.60)	
p-value [3]		0.069		0.660	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	59	115	4	10	
Mean (StdDev)	1.7 (1.23)	1.3 (1.26)	3.0 (0.00)	1.9 (1.37)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	3, 3	0, 4	
C5D1 CFB					
n	57	109	4	10	
LS Mean (StdErr) [2]	-0.14 (0.196)	-0.80 (0.150)	-0.80 (1.240)	-0.93 (0.949)	
95% CI [2]	-0.53, 0.24	-1.09, -0.50	-3.56, 1.97	-3.04, 1.19	
Difference (95% CI) in CFB [2]		-0.65 (-1.09, -0.22)		-0.13 (-2.42, 2.16)	
p-value [3]		0.003		0.902	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	1.8 (1.29)	1.3 (1.29)	3.3 (0.50)	1.9 (1.29)	
Median	2.0	1.0	3.0	1.5	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-0.17 (0.193)	-0.65 (0.145)	-0.69 (1.271)	-1.20 (0.973)	
95% CI [2]	-0.55, 0.22	-0.93, -0.36	-3.52, 2.15	-3.37, 0.96	
Difference (95% CI) in CFB [2]		-0.48 (-0.91, -0.06)		-0.52 (-2.87, 1.83)	
p-value [3]		0.027		0.634	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	1.5 (1.27)	1.3 (1.27)	3.3 (0.50)	1.8 (1.40)	
Median	1.0	1.0	3.0	1.5	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-0.26 (0.195)	-0.65 (0.148)	-0.04 (1.110)	-0.74 (0.850)	
95% CI [2]	-0.64, 0.13	-0.94, -0.36	-2.51, 2.44	-2.64, 1.15	
Difference (95% CI) in CFB [2]		-0.39 (-0.82, 0.03)		-0.70 (-2.76, 1.35)	
Hedges'G (95% CI) in CFB		-0.26 (-0.59, 0.06)		-0.26 (-1.60, 0.99)	
p-value [3]		0.070		0.463	
					0.763

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	2.5 (1.21)	2.6 (1.30)	3.0 (2.00)	3.4 (0.70)	
Median	3.0	3.0	4.0	3.5	
Min, Max	0, 4	0, 4	0, 4	2, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	2.2 (1.22)	2.0 (1.33)	3.5 (0.58)	2.6 (1.01)	
Median	2.0	2.0	3.5	2.0	
Min, Max	0, 4	0, 4	3, 4	1, 4	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	-0.25 (0.159)	-0.49 (0.122)	0.26 (0.901)	-1.07 (0.686)	
95% CI [2]	-0.56, 0.07	-0.73, -0.25	-1.78, 2.30	-2.62, 0.49	
Difference (95% CI) in CFB [2]		-0.25 (-0.60, 0.10)		-1.33 (-3.03, 0.38)	
p-value [3]		0.161		0.112	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	118	4	9	
Mean (StdDev)	2.2 (1.22)	1.8 (1.29)	3.3 (0.50)	2.6 (1.33)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-0.24 (0.166)	-0.69 (0.126)	-0.61 (0.927)	-1.60 (0.706)	
95% CI [2]	-0.57, 0.09	-0.94, -0.44	-2.71, 1.49	-3.19, -0.00	
Difference (95% CI) in CFB [2]		-0.45 (-0.82, -0.08)		-0.99 (-2.74, 0.77)	
p-value [3]		0.016		0.234	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	2.0 (1.32)	1.9 (1.33)	3.3 (0.50)	2.8 (1.32)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-0.36 (0.186)	-0.63 (0.138)	-0.65 (0.910)	-1.46 (0.696)	
95% CI [2]	-0.73, 0.01	-0.90, -0.36	-2.67, 1.38	-3.01, 0.09	
Difference (95% CI) in CFB [2]		-0.27 (-0.67, 0.14)		-0.81 (-2.50, 0.87)	
p-value [3]		0.192		0.306	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	59	115	4	10	
Mean (StdDev)	2.1 (1.22)	1.6 (1.21)	3.3 (0.50)	2.5 (1.35)	
Median	2.0	1.0	3.0	3.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C5D1 CFB					
n	57	109	4	10	
LS Mean (StdErr) [2]	-0.31 (0.176)	-0.87 (0.135)	0.04 (1.110)	-1.26 (0.850)	
95% CI [2]	-0.66, 0.03	-1.13, -0.60	-2.44, 2.51	-3.15, 0.64	
Difference (95% CI) in CFB [2]		-0.55 (-0.94, -0.16)		-1.30 (-3.35, 0.76)	
p-value [3]		0.006		0.190	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	2.3 (1.28)	1.6 (1.29)	3.5 (0.58)	2.7 (0.95)	
Median	2.0	1.0	3.5	3.0	
Min, Max	0, 4	0, 4	3, 4	1, 4	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-0.15 (0.178)	-0.80 (0.134)	0.74 (0.932)	-0.69 (0.714)	
95% CI [2]	-0.50, 0.20	-1.06, -0.54	-1.34, 2.82	-2.28, 0.91	
Difference (95% CI) in CFB [2]		-0.65 (-1.04, -0.26)		-1.43 (-3.15, 0.30)	
p-value [3]		0.001		0.095	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	2.0 (1.27)	1.7 (1.33)	3.5 (0.58)	2.7 (1.06)	
Median	2.0	1.0	3.5	3.0	
Min, Max	0, 4	0, 4	3, 4	1, 4	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-0.36 (0.192)	-0.79 (0.145)	0.11 (0.974)	-1.28 (0.746)	
95% CI [2]	-0.74, 0.02	-1.08, -0.51	-2.06, 2.28	-2.94, 0.38	
Difference (95% CI) in CFB [2]		-0.43 (-0.85, -0.02)		-1.39 (-3.19, 0.41)	
Hedges'G (95% CI) in CFB		-0.29 (-0.62, 0.03)		-0.57 (-2.01, 0.62)	
p-value [3]		0.042		0.117	
					0.300

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	2.3 (1.37)	2.4 (1.10)	3.5 (0.58)	2.9 (0.88)	
Median	3.0	2.0	3.5	3.0	
Min, Max	0, 4	0, 4	3, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	2.0 (1.19)	1.8 (1.20)	3.0 (0.82)	1.9 (1.54)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	-0.14 (0.156)	-0.44 (0.120)	-1.54 (1.203)	-1.74 (0.916)	
95% CI [2]	-0.44, 0.17	-0.68, -0.21	-4.26, 1.18	-3.81, 0.33	
Difference (95% CI) in CFB [2]		-0.31 (-0.65, 0.03)		-0.20 (-2.47, 2.08)	
p-value [3]		0.078		0.850	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	118	4	9	
Mean (StdDev)	1.8 (1.36)	1.7 (1.12)	3.0 (1.15)	1.8 (1.39)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-0.30 (0.154)	-0.55 (0.117)	0.04 (0.982)	-0.76 (0.748)	
95% CI [2]	-0.61, 0.00	-0.78, -0.32	-2.18, 2.26	-2.45, 0.93	
Difference (95% CI) in CFB [2]		-0.25 (-0.59, 0.09)		-0.80 (-2.66, 1.05)	
p-value [3]		0.146		0.353	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	1.9 (1.31)	1.7 (1.20)	3.8 (0.50)	1.9 (1.52)	
Median	2.0	2.0	4.0	1.5	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-0.35 (0.184)	-0.64 (0.137)	1.37 (1.094)	-0.09 (0.838)	
95% CI [2]	-0.71, 0.01	-0.91, -0.37	-1.07, 3.81	-1.96, 1.77	
Difference (95% CI) in CFB [2]		-0.29 (-0.69, 0.11)		-1.46 (-3.49, 0.56)	
p-value [3]		0.150		0.138	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	59	115	4	10	
Mean (StdDev)	1.9 (1.31)	1.6 (1.22)	3.5 (0.58)	1.4 (1.51)	
Median	2.0	2.0	3.5	1.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C5D1 CFB					
n	57	109	4	10	
LS Mean (StdErr) [2]	-0.16 (0.181)	-0.70 (0.139)	-0.89 (1.028)	-2.28 (0.787)	
95% CI [2]	-0.52, 0.20	-0.98, -0.43	-3.18, 1.40	-4.03, -0.52	
Difference (95% CI) in CFB [2]		-0.54 (-0.94, -0.14)		-1.39 (-3.29, 0.51)	
p-value [3]		0.009		0.135	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	2.1 (1.32)	1.5 (1.21)	3.5 (0.58)	1.6 (1.65)	
Median	2.0	2.0	3.5	1.5	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	0.00 (0.184)	-0.75 (0.138)	1.26 (1.092)	-0.31 (0.836)	
95% CI [2]	-0.36, 0.37	-1.02, -0.48	-1.17, 3.69	-2.18, 1.55	
Difference (95% CI) in CFB [2]		-0.75 (-1.16, -0.35)		-1.57 (-3.59, 0.45)	
p-value [3]		<0.001		0.113	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	1.9 (1.34)	1.6 (1.26)	3.0 (0.82)	2.0 (1.49)	
Median	2.0	2.0	3.0	2.5	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-0.14 (0.187)	-0.67 (0.141)	-0.06 (1.197)	-0.61 (0.916)	
95% CI [2]	-0.51, 0.23	-0.95, -0.39	-2.72, 2.61	-2.65, 1.43	
Difference (95% CI) in CFB [2]		-0.54 (-0.95, -0.13)		-0.56 (-2.77, 1.66)	
Hedges'G (95% CI) in CFB		-0.37 (-0.70, -0.05)		-0.19 (-1.52, 1.07)	
p-value [3]		0.010		0.588	
					0.884

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	1.6 (1.51)	1.8 (1.46)	3.5 (1.00)	2.7 (1.57)	
Median	1.0	2.0	4.0	3.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	1.7 (1.50)	1.5 (1.41)	3.3 (0.50)	2.6 (1.51)	
Median	1.0	1.0	3.0	3.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	0.03 (0.145)	-0.29 (0.111)	-0.41 (1.168)	-0.27 (0.889)	
95% CI [2]	-0.26, 0.31	-0.51, -0.07	-3.05, 2.23	-2.28, 1.74	
Difference (95% CI) in CFB [2]		-0.32 (-0.63, 0.00)		0.14 (-2.07, 2.35)	
p-value [3]		0.052		0.888	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	118	4	9	
Mean (StdDev)	1.4 (1.54)	1.3 (1.35)	2.8 (1.26)	2.6 (1.33)	
Median	1.0	1.0	3.0	3.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-0.12 (0.151)	-0.39 (0.114)	-0.85 (1.152)	-0.16 (0.877)	
95% CI [2]	-0.42, 0.18	-0.61, -0.16	-3.45, 1.76	-2.15, 1.82	
Difference (95% CI) in CFB [2]		-0.27 (-0.60, 0.07)		0.68 (-1.50, 2.86)	
p-value [3]		0.116		0.495	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	1.5 (1.32)	1.2 (1.35)	3.0 (0.82)	2.3 (1.57)	
Median	1.0	1.0	3.0	2.5	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-0.16 (0.185)	-0.40 (0.137)	-0.43 (1.481)	-0.52 (1.134)	
95% CI [2]	-0.53, 0.20	-0.67, -0.13	-3.73, 2.87	-3.05, 2.01	
Difference (95% CI) in CFB [2]		-0.24 (-0.64, 0.16)		-0.09 (-2.83, 2.65)	
p-value [3]		0.238		0.941	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	59	114	4	10	
Mean (StdDev)	1.3 (1.39)	1.2 (1.25)	2.8 (0.50)	2.6 (1.43)	
Median	1.0	1.0	3.0	2.5	
Min, Max	0, 4	0, 4	2, 3	0, 4	
C5D1 CFB					
n	57	108	4	10	
LS Mean (StdErr) [2]	-0.15 (0.186)	-0.52 (0.143)	-0.81 (1.353)	-0.30 (1.036)	
95% CI [2]	-0.52, 0.21	-0.81, -0.24	-3.83, 2.20	-2.60, 2.01	
Difference (95% CI) in CFB [2]		-0.37 (-0.78, 0.04)		0.52 (-1.98, 3.02)	
p-value [3]		0.076		0.654	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	1.4 (1.40)	1.1 (1.35)	1.8 (1.26)	3.2 (0.79)	
Median	1.0	1.0	2.0	3.0	
Min, Max	0, 4	0, 4	0, 3	2, 4	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-0.17 (0.196)	-0.58 (0.147)	-1.06 (1.241)	0.89 (0.950)	
95% CI [2]	-0.56, 0.22	-0.87, -0.29	-3.82, 1.71	-1.23, 3.01	
Difference (95% CI) in CFB [2]		-0.41 (-0.84, 0.03)		1.94 (-0.35, 4.24)	
p-value [3]		0.066		0.088	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	1.4 (1.42)	1.2 (1.36)	2.0 (1.41)	2.8 (1.23)	
Median	1.0	1.0	2.5	3.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	0.03 (0.190)	-0.41 (0.143)	-1.63 (1.296)	-0.09 (0.993)	
95% CI [2]	-0.35, 0.40	-0.69, -0.13	-4.52, 1.26	-2.30, 2.12	
Difference (95% CI) in CFB [2]		-0.44 (-0.85, -0.02)		1.54 (-0.86, 3.94)	
Hedges'G (95% CI) in CFB		-0.29 (-0.62, 0.03)		0.48 (-0.73, 1.88)	
p-value [3]		0.038		0.184	
					0.014

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	2.1 (1.26)	2.3 (1.19)	3.8 (0.50)	2.8 (0.92)	
Median	2.0	2.0	4.0	3.0	
Min, Max	0, 4	0, 4	3, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	1.7 (1.20)	1.8 (1.20)	3.3 (0.50)	2.3 (0.87)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	3, 4	1, 4	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	-0.35 (0.129)	-0.50 (0.099)	-0.24 (0.517)	-0.07 (0.394)	
95% CI [2]	-0.60, -0.10	-0.69, -0.31	-1.41, 0.93	-0.96, 0.83	
Difference (95% CI) in CFB [2]		-0.15 (-0.43, 0.13)		0.17 (-0.81, 1.15)	
p-value [3]		0.297		0.697	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	118	4	9	
Mean (StdDev)	1.8 (1.28)	1.5 (1.24)	3.0 (0.82)	2.2 (1.39)	
Median	2.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-0.21 (0.145)	-0.73 (0.110)	-1.15 (0.694)	-0.84 (0.528)	
95% CI [2]	-0.50, 0.07	-0.95, -0.51	-2.72, 0.42	-2.03, 0.36	
Difference (95% CI) in CFB [2]		-0.52 (-0.84, -0.20)		0.32 (-1.00, 1.63)	
p-value [3]		0.002		0.600	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	1.8 (1.18)	1.4 (1.15)	3.0 (0.00)	2.5 (1.27)	
Median	2.0	1.0	3.0	3.0	
Min, Max	0, 4	0, 4	3, 3	0, 4	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-0.25 (0.150)	-0.77 (0.111)	-1.13 (0.480)	-0.59 (0.368)	
95% CI [2]	-0.54, 0.05	-0.99, -0.55	-2.20, -0.06	-1.41, 0.23	
Difference (95% CI) in CFB [2]		-0.52 (-0.85, -0.20)		0.54 (-0.35, 1.43)	
p-value [3]		0.002		0.208	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	59	115	4	10	
Mean (StdDev)	1.7 (1.18)	1.4 (1.17)	3.3 (0.50)	2.4 (1.43)	
Median	1.0	1.0	3.0	2.5	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C5D1 CFB					
n	57	109	4	10	
LS Mean (StdErr) [2]	-0.40 (0.160)	-0.97 (0.123)	-0.89 (0.598)	-0.78 (0.458)	
95% CI [2]	-0.71, -0.08	-1.21, -0.72	-2.22, 0.44	-1.80, 0.24	
Difference (95% CI) in CFB [2]		-0.57 (-0.92, -0.22)		0.11 (-1.00, 1.22)	
p-value [3]		0.002		0.828	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	1.9 (1.21)	1.4 (1.27)	3.3 (0.50)	2.9 (0.99)	
Median	2.0	1.0	3.0	3.0	
Min, Max	0, 4	0, 4	3, 4	1, 4	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-0.08 (0.164)	-0.89 (0.123)	0.00 (0.401)	0.50 (0.307)	
95% CI [2]	-0.40, 0.24	-1.14, -0.65	-0.89, 0.89	-0.18, 1.18	
Difference (95% CI) in CFB [2]		-0.81 (-1.18, -0.45)		0.50 (-0.24, 1.24)	
p-value [3]		<0.0001		0.165	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	1.8 (1.33)	1.4 (1.28)	3.5 (0.58)	2.1 (1.45)	
Median	2.0	1.0	3.5	2.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-0.19 (0.162)	-0.77 (0.122)	-0.56 (0.598)	-1.11 (0.458)	
95% CI [2]	-0.51, 0.13	-1.01, -0.53	-1.89, 0.78	-2.13, -0.09	
Difference (95% CI) in CFB [2]		-0.58 (-0.94, -0.23)		-0.56 (-1.66, 0.55)	
Hedges'G (95% CI) in CFB		-0.46 (-0.79, -0.14)		-0.37 (-1.75, 0.85)	
p-value [3]		0.001		0.290	
					0.913

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	1.8 (1.34)	2.0 (1.29)	4.0 (0.00)	2.7 (1.25)	
Median	2.0	2.0	4.0	3.0	
Min, Max	0, 4	0, 4	4, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	1.4 (1.15)	1.5 (1.25)	3.0 (0.82)	2.0 (1.32)	
Median	1.0	1.0	3.0	2.0	
Min, Max	0, 3	0, 4	2, 4	0, 4	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	-0.36 (0.143)	-0.45 (0.109)	-0.57 (0.634)	-0.11 (0.483)	
95% CI [2]	-0.64, -0.08	-0.66, -0.23	-2.00, 0.87	-1.20, 0.98	
Difference (95% CI) in CFB [2]		-0.09 (-0.40, 0.23)		0.46 (-0.74, 1.66)	
p-value [3]		0.582		0.412	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	118	4	9	
Mean (StdDev)	1.5 (1.28)	1.4 (1.26)	2.8 (0.50)	1.8 (1.56)	
Median	1.0	1.0	3.0	2.0	
Min, Max	0, 4	0, 4	2, 3	0, 4	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-0.23 (0.143)	-0.60 (0.109)	-0.93 (0.712)	-0.64 (0.542)	
95% CI [2]	-0.51, 0.06	-0.81, -0.38	-2.55, 0.68	-1.87, 0.59	
Difference (95% CI) in CFB [2]		-0.37 (-0.69, -0.05)		0.29 (-1.05, 1.64)	
p-value [3]		0.022		0.634	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	1.4 (1.06)	1.2 (1.20)	3.5 (0.58)	2.2 (1.40)	
Median	1.5	1.0	3.5	2.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-0.39 (0.155)	-0.75 (0.115)	-0.19 (0.616)	-0.20 (0.472)	
95% CI [2]	-0.70, -0.09	-0.97, -0.52	-1.56, 1.19	-1.26, 0.85	
Difference (95% CI) in CFB [2]		-0.35 (-0.69, -0.02)		-0.02 (-1.16, 1.12)	
p-value [3]		0.039		0.972	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	59	115	4	10	
Mean (StdDev)	1.4 (1.29)	1.2 (1.14)	3.0 (0.00)	2.3 (1.57)	
Median	1.0	1.0	3.0	2.5	
Min, Max	0, 4	0, 4	3, 3	0, 4	
C5D1 CFB					
n	57	109	4	10	
LS Mean (StdErr) [2]	-0.28 (0.166)	-0.85 (0.128)	-0.81 (0.468)	-0.30 (0.358)	
95% CI [2]	-0.60, 0.05	-1.10, -0.60	-1.86, 0.23	-1.09, 0.50	
Difference (95% CI) in CFB [2]		-0.57 (-0.94, -0.21)		0.52 (-0.35, 1.38)	
p-value [3]		0.002		0.212	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	1.5 (1.17)	1.2 (1.27)	3.8 (0.50)	2.4 (1.43)	
Median	1.0	1.0	4.0	2.5	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-0.24 (0.163)	-0.85 (0.122)	0.93 (0.561)	0.52 (0.429)	
95% CI [2]	-0.56, 0.09	-1.09, -0.61	-0.32, 2.18	-0.44, 1.47	
Difference (95% CI) in CFB [2]		-0.61 (-0.97, -0.25)		-0.41 (-1.44, 0.63)	
p-value [3]		<0.001		0.402	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	1.4 (1.26)	1.2 (1.28)	3.5 (0.58)	2.0 (1.63)	
Median	1.0	1.0	3.5	2.5	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-0.15 (0.165)	-0.69 (0.124)	-0.20 (0.719)	-0.57 (0.551)	
95% CI [2]	-0.48, 0.18	-0.94, -0.45	-1.81, 1.40	-1.80, 0.65	
Difference (95% CI) in CFB [2]		-0.54 (-0.90, -0.18)		-0.37 (-1.70, 0.96)	
Hedges'G (95% CI) in CFB		-0.42 (-0.75, -0.10)		-0.21 (-1.54, 1.04)	
p-value [3]		0.003		0.549	
					0.610

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	2.9 (0.94)	2.8 (1.02)	3.8 (0.50)	2.9 (1.20)	
Median	3.0	3.0	4.0	3.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	2.5 (1.06)	2.5 (1.01)	3.5 (0.58)	2.2 (1.20)	
Median	3.0	2.5	3.5	2.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	-0.49 (0.129)	-0.40 (0.099)	-1.07 (0.516)	-1.36 (0.393)	
95% CI [2]	-0.74, -0.23	-0.59, -0.20	-2.23, 0.10	-2.25, -0.47	
Difference (95% CI) in CFB [2]		0.09 (-0.19, 0.37)		-0.29 (-1.27, 0.68)	
p-value [3]		0.537		0.513	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	118	4	9	
Mean (StdDev)	2.5 (1.08)	2.2 (1.13)	3.0 (1.15)	2.0 (1.50)	
Median	3.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-0.35 (0.137)	-0.55 (0.104)	-0.35 (0.918)	-0.66 (0.699)	
95% CI [2]	-0.62, -0.08	-0.76, -0.35	-2.43, 1.73	-2.25, 0.92	
Difference (95% CI) in CFB [2]		-0.21 (-0.51, 0.10)		-0.32 (-2.05, 1.42)	
p-value [3]		0.180		0.691	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	2.3 (1.23)	2.3 (1.24)	3.8 (0.50)	2.4 (1.07)	
Median	2.0	2.0	4.0	2.0	
Min, Max	0, 4	0, 4	3, 4	1, 4	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-0.62 (0.159)	-0.48 (0.118)	0.37 (0.845)	-0.09 (0.647)	
95% CI [2]	-0.93, -0.31	-0.71, -0.24	-1.51, 2.25	-1.53, 1.35	
Difference (95% CI) in CFB [2]		0.14 (-0.20, 0.49)		-0.46 (-2.03, 1.10)	
p-value [3]		0.414		0.524	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	115	4	10	
Mean (StdDev)	2.4 (1.08)	2.1 (1.24)	3.5 (0.58)	1.4 (1.51)	
Median	2.0	2.0	3.5	1.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C5D1 CFB					
n	58	109	4	10	
LS Mean (StdErr) [2]	-0.52 (0.164)	-0.76 (0.127)	-1.69 (1.038)	-2.70 (0.795)	
95% CI [2]	-0.85, -0.20	-1.01, -0.51	-4.00, 0.63	-4.47, -0.93	
Difference (95% CI) in CFB [2]		-0.24 (-0.60, 0.13)		-1.02 (-2.94, 0.90)	
p-value [3]		0.201		0.265	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	2.4 (1.22)	2.1 (1.23)	3.5 (0.58)	1.7 (1.34)	
Median	2.0	2.0	3.5	1.5	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-0.32 (0.168)	-0.60 (0.126)	-0.13 (0.936)	-1.09 (0.716)	
95% CI [2]	-0.65, 0.01	-0.85, -0.35	-2.21, 1.95	-2.69, 0.50	
Difference (95% CI) in CFB [2]		-0.27 (-0.65, 0.10)		-0.96 (-2.69, 0.77)	
p-value [3]		0.145		0.243	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	2.4 (1.12)	2.1 (1.15)	3.3 (0.96)	2.3 (1.42)	
Median	2.5	2.0	3.5	2.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-0.40 (0.165)	-0.64 (0.125)	-0.17 (0.955)	-0.33 (0.732)	
95% CI [2]	-0.73, -0.07	-0.89, -0.40	-2.30, 1.96	-1.96, 1.30	
Difference (95% CI) in CFB [2]		-0.25 (-0.61, 0.11)		-0.17 (-1.93, 1.60)	
Hedges'G (95% CI) in CFB		-0.19 (-0.52, 0.13)		-0.07 (-1.37, 1.20)	
p-value [3]		0.181		0.838	
					0.849

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	2.4 (1.45)	2.4 (1.20)	3.0 (2.00)	2.6 (1.35)	
Median	3.0	2.0	4.0	2.5	
Min, Max	0, 4	0, 4	0, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	2.1 (1.27)	1.9 (1.32)	2.5 (1.29)	2.2 (1.39)	
Median	2.0	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	-0.28 (0.144)	-0.53 (0.111)	-0.91 (0.845)	-0.52 (0.644)	
95% CI [2]	-0.56, 0.01	-0.75, -0.31	-2.82, 1.00	-1.98, 0.93	
Difference (95% CI) in CFB [2]		-0.25 (-0.57, 0.07)		0.39 (-1.21, 1.99)	
p-value [3]		0.121		0.593	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	118	4	9	
Mean (StdDev)	2.2 (1.25)	1.8 (1.26)	3.3 (0.96)	2.1 (1.36)	
Median	2.0	2.0	3.5	2.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-0.24 (0.162)	-0.70 (0.123)	0.80 (0.838)	-0.08 (0.638)	
95% CI [2]	-0.56, 0.08	-0.94, -0.45	-1.09, 2.70	-1.52, 1.37	
Difference (95% CI) in CFB [2]		-0.46 (-0.82, -0.10)		-0.88 (-2.47, 0.70)	
p-value [3]		0.012		0.241	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	2.0 (1.35)	1.8 (1.37)	2.8 (1.50)	2.5 (1.35)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-0.37 (0.160)	-0.66 (0.119)	-0.31 (0.658)	-0.30 (0.504)	
95% CI [2]	-0.69, -0.06	-0.89, -0.42	-1.78, 1.15	-1.42, 0.83	
Difference (95% CI) in CFB [2]		-0.28 (-0.63, 0.06)		0.02 (-1.20, 1.24)	
p-value [3]		0.109		0.974	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	115	4	10	
Mean (StdDev)	1.9 (1.45)	1.7 (1.39)	3.0 (2.00)	2.3 (1.77)	
Median	2.0	2.0	4.0	2.5	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	58	109	4	10	
LS Mean (StdErr) [2]	-0.44 (0.166)	-0.79 (0.128)	-0.46 (0.612)	-0.76 (0.468)	
95% CI [2]	-0.77, -0.11	-1.04, -0.53	-1.83, 0.90	-1.80, 0.28	
Difference (95% CI) in CFB [2]		-0.34 (-0.71, 0.02)		-0.30 (-1.43, 0.84)	
p-value [3]		0.066		0.573	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	2.2 (1.31)	1.6 (1.32)	2.8 (1.89)	2.1 (1.73)	
Median	2.0	1.0	3.5	2.5	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-0.15 (0.169)	-0.85 (0.126)	-0.59 (0.368)	-0.85 (0.282)	
95% CI [2]	-0.49, 0.18	-1.10, -0.61	-1.41, 0.23	-1.48, -0.22	
Difference (95% CI) in CFB [2]		-0.70 (-1.07, -0.33)		-0.26 (-0.94, 0.42)	
p-value [3]		<0.001		0.416	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	2.0 (1.43)	1.4 (1.37)	2.8 (1.89)	2.1 (1.60)	
Median	2.0	1.0	3.5	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-0.37 (0.181)	-0.89 (0.136)	0.04 (0.399)	-0.26 (0.305)	
95% CI [2]	-0.73, -0.02	-1.16, -0.62	-0.85, 0.93	-0.94, 0.42	
Difference (95% CI) in CFB [2]		-0.52 (-0.91, -0.13)		-0.30 (-1.03, 0.44)	
Hedges'G (95% CI) in CFB		-0.37 (-0.70, -0.05)		-0.30 (-1.66, 0.94)	
p-value [3]		0.010		0.392	
					0.767

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	2.8 (1.13)	2.9 (1.01)	3.8 (0.50)	3.2 (0.63)	
Median	3.0	3.0	4.0	3.0	
Min, Max	0, 4	0, 4	3, 4	2, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	2.2 (1.10)	2.2 (1.24)	3.5 (0.58)	2.8 (0.83)	
Median	2.0	2.0	3.5	3.0	
Min, Max	0, 4	0, 4	3, 4	2, 4	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	-0.60 (0.137)	-0.72 (0.105)	-0.07 (0.622)	-0.36 (0.474)	
95% CI [2]	-0.87, -0.33	-0.93, -0.52	-1.47, 1.34	-1.43, 0.71	
Difference (95% CI) in CFB [2]		-0.12 (-0.43, 0.18)		-0.29 (-1.47, 0.88)	
p-value [3]		0.417		0.586	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	118	4	9	
Mean (StdDev)	2.4 (1.21)	1.9 (1.20)	2.8 (0.96)	2.7 (0.87)	
Median	2.0	2.0	2.5	3.0	
Min, Max	0, 4	0, 4	2, 4	1, 4	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-0.37 (0.152)	-0.91 (0.115)	-0.17 (0.664)	0.04 (0.506)	
95% CI [2]	-0.67, -0.07	-1.14, -0.69	-1.68, 1.33	-1.10, 1.19	
Difference (95% CI) in CFB [2]		-0.54 (-0.88, -0.21)		0.22 (-1.04, 1.47)	
p-value [3]		0.002		0.705	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	2.4 (1.14)	2.0 (1.23)	3.8 (0.50)	2.5 (1.18)	
Median	2.0	2.0	4.0	3.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-0.43 (0.163)	-0.91 (0.121)	-0.17 (0.733)	-0.83 (0.561)	
95% CI [2]	-0.75, -0.11	-1.14, -0.67	-1.80, 1.47	-2.08, 0.42	
Difference (95% CI) in CFB [2]		-0.48 (-0.83, -0.12)		-0.67 (-2.02, 0.69)	
p-value [3]		0.009		0.299	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	114	4	10	
Mean (StdDev)	2.2 (1.17)	1.9 (1.17)	3.5 (0.58)	2.5 (1.35)	
Median	2.0	2.0	3.5	2.5	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C5D1 CFB					
n	58	108	4	10	
LS Mean (StdErr) [2]	-0.48 (0.155)	-1.00 (0.120)	-0.44 (0.825)	-0.89 (0.631)	
95% CI [2]	-0.79, -0.18	-1.24, -0.76	-2.28, 1.39	-2.30, 0.52	
Difference (95% CI) in CFB [2]		-0.52 (-0.86, -0.17)		-0.44 (-1.97, 1.08)	
p-value [3]		0.003		0.531	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	2.4 (1.14)	1.8 (1.30)	3.8 (0.50)	2.5 (1.08)	
Median	2.0	2.0	4.0	2.5	
Min, Max	0, 4	0, 4	3, 4	1, 4	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-0.35 (0.167)	-1.10 (0.125)	0.24 (0.621)	-0.69 (0.476)	
95% CI [2]	-0.68, -0.03	-1.34, -0.85	-1.14, 1.62	-1.74, 0.37	
Difference (95% CI) in CFB [2]		-0.74 (-1.11, -0.37)		-0.93 (-2.08, 0.22)	
p-value [3]		<0.001		0.103	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	2.2 (1.32)	1.8 (1.30)	3.3 (0.50)	2.3 (1.06)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-0.41 (0.168)	-0.93 (0.127)	-0.06 (0.757)	-0.61 (0.579)	
95% CI [2]	-0.74, -0.08	-1.18, -0.68	-1.74, 1.63	-1.90, 0.68	
Difference (95% CI) in CFB [2]		-0.52 (-0.88, -0.15)		-0.56 (-1.96, 0.84)	
Hedges'G (95% CI) in CFB		-0.39 (-0.73, -0.07)		-0.30 (-1.65, 0.94)	
p-value [3]		0.006		0.398	
					0.848

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	3.0 (0.93)	3.0 (0.98)	4.0 (0.00)	3.3 (0.67)	
Median	3.0	3.0	4.0	3.0	
Min, Max	0, 4	0, 4	4, 4	2, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	2.5 (0.99)	2.3 (1.09)	3.5 (0.58)	3.1 (0.78)	
Median	3.0	2.0	3.5	3.0	
Min, Max	0, 4	0, 4	3, 4	2, 4	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	-0.41 (0.132)	-0.75 (0.101)	-0.26 (0.573)	0.07 (0.436)	
95% CI [2]	-0.67, -0.15	-0.95, -0.55	-1.56, 1.04	-0.92, 1.05	
Difference (95% CI) in CFB [2]		-0.34 (-0.63, -0.05)		0.33 (-0.76, 1.41)	
p-value [3]		0.023		0.513	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	118	4	9	
Mean (StdDev)	2.4 (1.10)	2.0 (1.18)	3.0 (0.82)	2.6 (1.13)	
Median	3.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	2, 4	1, 4	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-0.47 (0.157)	-0.94 (0.120)	-0.59 (0.642)	-0.48 (0.489)	
95% CI [2]	-0.78, -0.16	-1.18, -0.71	-2.04, 0.87	-1.58, 0.63	
Difference (95% CI) in CFB [2]		-0.47 (-0.82, -0.13)		0.11 (-1.11, 1.32)	
p-value [3]		0.008		0.844	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	2.4 (1.15)	2.0 (1.15)	3.3 (0.96)	2.8 (0.92)	
Median	2.0	2.0	3.5	3.0	
Min, Max	0, 4	0, 4	2, 4	1, 4	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-0.59 (0.160)	-1.07 (0.118)	-0.46 (0.612)	-0.26 (0.468)	
95% CI [2]	-0.91, -0.28	-1.31, -0.84	-1.83, 0.90	-1.30, 0.78	
Difference (95% CI) in CFB [2]		-0.48 (-0.83, -0.14)		0.20 (-0.93, 1.34)	
p-value [3]		0.007		0.697	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	115	4	10	
Mean (StdDev)	2.3 (1.29)	2.0 (1.17)	3.3 (0.96)	2.9 (1.29)	
Median	2.5	2.0	3.5	3.5	
Min, Max	0, 4	0, 4	2, 4	1, 4	
C5D1 CFB					
n	58	109	4	10	
LS Mean (StdErr) [2]	-0.56 (0.168)	-1.04 (0.129)	-1.11 (0.682)	-0.72 (0.522)	
95% CI [2]	-0.89, -0.23	-1.29, -0.78	-2.63, 0.41	-1.89, 0.44	
Difference (95% CI) in CFB [2]		-0.47 (-0.84, -0.10)		0.39 (-0.87, 1.65)	
p-value [3]		0.012		0.508	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	2.5 (1.13)	1.9 (1.27)	3.5 (1.00)	2.5 (1.08)	
Median	2.5	2.0	4.0	2.5	
Min, Max	0, 4	0, 4	2, 4	1, 4	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-0.45 (0.172)	-1.11 (0.129)	-0.07 (0.727)	-0.48 (0.557)	
95% CI [2]	-0.79, -0.11	-1.37, -0.86	-1.69, 1.55	-1.72, 0.76	
Difference (95% CI) in CFB [2]		-0.67 (-1.05, -0.29)		-0.41 (-1.75, 0.94)	
p-value [3]		<0.001		0.515	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	2.3 (1.35)	1.9 (1.23)	3.0 (0.82)	2.4 (1.35)	
Median	2.5	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-0.54 (0.176)	-1.04 (0.133)	-0.50 (0.803)	-0.50 (0.615)	
95% CI [2]	-0.89, -0.19	-1.30, -0.78	-2.29, 1.29	-1.87, 0.87	
Difference (95% CI) in CFB [2]		-0.50 (-0.88, -0.12)		0.00 (-1.49, 1.49)	
Hedges'G (95% CI) in CFB		-0.37 (-0.70, -0.04)		-0.00 (-1.29, 1.29)	
p-value [3]		0.010		>0.999	
					0.391

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	2.1 (1.50)	1.8 (1.47)	3.3 (0.96)	2.5 (1.27)	
Median	2.0	2.0	3.5	2.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	1.9 (1.45)	1.4 (1.40)	2.0 (1.15)	1.8 (1.09)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 3	0, 3	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	0.03 (0.160)	-0.19 (0.123)	-0.78 (0.941)	-0.05 (0.717)	
95% CI [2]	-0.28, 0.35	-0.43, 0.05	-2.91, 1.35	-1.68, 1.57	
Difference (95% CI) in CFB [2]		-0.22 (-0.57, 0.13)		0.73 (-1.05, 2.51)	
p-value [3]		0.219		0.379	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	118	4	9	
Mean (StdDev)	1.9 (1.42)	1.3 (1.36)	2.5 (1.00)	1.0 (1.50)	
Median	2.0	1.0	3.0	0.0	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-0.04 (0.178)	-0.32 (0.135)	-0.07 (0.933)	-0.86 (0.710)	
95% CI [2]	-0.39, 0.31	-0.59, -0.06	-2.17, 2.04	-2.47, 0.75	
Difference (95% CI) in CFB [2]		-0.28 (-0.67, 0.11)		-0.79 (-2.56, 0.97)	
p-value [3]		0.156		0.336	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	1.8 (1.31)	1.4 (1.36)	2.0 (0.82)	1.7 (1.77)	
Median	2.0	1.0	2.0	1.5	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-0.12 (0.175)	-0.25 (0.130)	-0.91 (0.997)	-0.65 (0.764)	
95% CI [2]	-0.46, 0.23	-0.50, 0.01	-3.13, 1.31	-2.35, 1.05	
Difference (95% CI) in CFB [2]		-0.13 (-0.51, 0.25)		0.26 (-1.59, 2.10)	
p-value [3]		0.507		0.761	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	115	4	10	
Mean (StdDev)	1.7 (1.36)	1.3 (1.33)	2.8 (0.96)	1.7 (1.83)	
Median	2.0	1.0	2.5	1.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C5D1 CFB					
n	58	109	4	10	
LS Mean (StdErr) [2]	-0.16 (0.191)	-0.28 (0.147)	-0.13 (1.018)	-0.59 (0.779)	
95% CI [2]	-0.54, 0.21	-0.57, 0.01	-2.40, 2.14	-2.33, 1.14	
Difference (95% CI) in CFB [2]		-0.12 (-0.54, 0.31)		-0.46 (-2.35, 1.42)	
p-value [3]		0.589		0.596	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	1.8 (1.44)	1.3 (1.31)	2.0 (1.83)	1.4 (1.51)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-0.16 (0.196)	-0.38 (0.147)	-0.57 (0.979)	-0.48 (0.750)	
95% CI [2]	-0.55, 0.22	-0.67, -0.09	-2.76, 1.61	-2.15, 1.19	
Difference (95% CI) in CFB [2]		-0.21 (-0.64, 0.22)		0.09 (-1.72, 1.90)	
p-value [3]		0.334		0.912	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	1.8 (1.50)	1.2 (1.26)	2.8 (1.26)	1.7 (1.83)	
Median	2.0	1.0	3.0	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	0.06 (0.200)	-0.30 (0.151)	-0.13 (0.845)	-0.59 (0.647)	
95% CI [2]	-0.33, 0.46	-0.60, 0.00	-2.01, 1.75	-2.03, 0.85	
Difference (95% CI) in CFB [2]		-0.36 (-0.80, 0.07)		-0.46 (-2.03, 1.10)	
Hedges'G (95% CI) in CFB		-0.23 (-0.56, 0.09)		-0.22 (-1.56, 1.03)	
p-value [3]		0.103		0.524	
					0.916

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	1.7 (1.28)	1.7 (1.29)	1.3 (0.50)	2.1 (1.52)	
Median	2.0	2.0	1.0	2.5	
Min, Max	0, 4	0, 4	1, 2	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	1.5 (1.13)	1.3 (1.21)	1.5 (0.58)	1.8 (1.48)	
Median	1.0	1.0	1.5	2.0	
Min, Max	0, 4	0, 4	1, 2	0, 4	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	-0.32 (0.120)	-0.46 (0.092)	0.33 (0.495)	-0.21 (0.377)	
95% CI [2]	-0.55, -0.08	-0.64, -0.28	-0.79, 1.45	-1.06, 0.65	
Difference (95% CI) in CFB [2]		-0.14 (-0.41, 0.12)		-0.53 (-1.47, 0.40)	
p-value [3]		0.290		0.230	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	118	4	9	
Mean (StdDev)	1.5 (1.19)	1.0 (1.12)	1.5 (1.00)	1.7 (1.66)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-0.30 (0.159)	-0.73 (0.121)	0.28 (0.531)	-0.45 (0.404)	
95% CI [2]	-0.61, 0.01	-0.97, -0.49	-0.92, 1.48	-1.36, 0.47	
Difference (95% CI) in CFB [2]		-0.43 (-0.78, -0.08)		-0.73 (-1.73, 0.28)	
p-value [3]		0.016		0.135	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	1.5 (1.21)	1.0 (1.13)	1.5 (1.00)	1.6 (1.43)	
Median	1.5	1.0	1.0	1.5	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-0.27 (0.173)	-0.73 (0.128)	0.48 (0.505)	-0.37 (0.386)	
95% CI [2]	-0.61, 0.07	-0.98, -0.47	-0.64, 1.61	-1.23, 0.49	
Difference (95% CI) in CFB [2]		-0.46 (-0.83, -0.08)		-0.85 (-1.79, 0.08)	
p-value [3]		0.017		0.069	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	115	4	10	
Mean (StdDev)	1.5 (1.17)	0.9 (1.13)	1.5 (1.00)	1.8 (1.48)	
Median	1.0	1.0	1.0	2.0	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C5D1 CFB					
n	58	109	4	10	
LS Mean (StdErr) [2]	-0.36 (0.157)	-0.83 (0.121)	0.33 (0.655)	-0.33 (0.502)	
95% CI [2]	-0.67, -0.05	-1.07, -0.59	-1.13, 1.79	-1.45, 0.78	
Difference (95% CI) in CFB [2]		-0.47 (-0.81, -0.12)		-0.67 (-1.88, 0.55)	
p-value [3]		0.009		0.249	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	1.5 (1.14)	1.0 (1.14)	1.5 (1.73)	1.8 (1.48)	
Median	1.0	1.0	1.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-0.29 (0.154)	-0.73 (0.116)	0.44 (0.946)	-0.11 (0.724)	
95% CI [2]	-0.60, 0.01	-0.96, -0.50	-1.66, 2.55	-1.73, 1.50	
Difference (95% CI) in CFB [2]		-0.43 (-0.77, -0.09)		-0.56 (-2.31, 1.20)	
p-value [3]		0.013		0.496	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	1.3 (1.13)	0.9 (1.09)	1.5 (1.00)	1.6 (1.43)	
Median	1.0	1.0	1.0	1.5	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-0.42 (0.159)	-0.70 (0.120)	0.43 (0.649)	-0.48 (0.497)	
95% CI [2]	-0.74, -0.11	-0.94, -0.46	-1.02, 1.87	-1.59, 0.63	
Difference (95% CI) in CFB [2]		-0.27 (-0.62, 0.07)		-0.91 (-2.11, 0.29)	
Hedges'G (95% CI) in CFB		-0.22 (-0.55, 0.10)		-0.56 (-1.99, 0.64)	
p-value [3]		0.122		0.123	
					0.506

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	1.2 (1.26)	1.3 (1.41)	1.5 (1.73)	2.4 (1.71)	
Median	1.0	1.0	1.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	1.1 (1.32)	1.1 (1.28)	1.5 (1.73)	2.0 (1.94)	
Median	1.0	1.0	1.0	3.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	0.01 (0.144)	-0.15 (0.110)	0.04 (0.813)	-0.26 (0.619)	
95% CI [2]	-0.28, 0.29	-0.37, 0.07	-1.80, 1.88	-1.66, 1.14	
Difference (95% CI) in CFB [2]		-0.16 (-0.47, 0.16)		-0.30 (-1.84, 1.24)	
p-value [3]		0.327		0.665	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	118	4	9	
Mean (StdDev)	1.0 (1.19)	0.9 (1.17)	1.3 (1.26)	1.3 (1.50)	
Median	1.0	0.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-0.11 (0.158)	-0.35 (0.120)	0.22 (0.802)	-0.55 (0.611)	
95% CI [2]	-0.42, 0.20	-0.59, -0.12	-1.60, 2.03	-1.94, 0.83	
Difference (95% CI) in CFB [2]		-0.24 (-0.59, 0.11)		-0.77 (-2.29, 0.75)	
p-value [3]		0.173		0.280	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	1.3 (1.25)	0.9 (1.12)	2.0 (1.41)	1.8 (1.75)	
Median	1.0	0.0	1.5	1.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-0.05 (0.168)	-0.50 (0.125)	0.67 (0.655)	-0.67 (0.502)	
95% CI [2]	-0.39, 0.28	-0.74, -0.25	-0.79, 2.13	-1.78, 0.45	
Difference (95% CI) in CFB [2]		-0.44 (-0.81, -0.08)		-1.33 (-2.55, -0.12)	
p-value [3]		0.018		0.034	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	115	4	10	
Mean (StdDev)	1.1 (1.23)	0.8 (1.10)	1.5 (1.73)	1.9 (1.66)	
Median	1.0	0.0	1.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	58	109	4	10	
LS Mean (StdErr) [2]	-0.05 (0.154)	-0.52 (0.119)	0.15 (0.487)	-0.54 (0.372)	
95% CI [2]	-0.35, 0.26	-0.75, -0.29	-0.94, 1.23	-1.37, 0.29	
Difference (95% CI) in CFB [2]		-0.47 (-0.81, -0.13)		-0.69 (-1.59, 0.22)	
p-value [3]		0.007		0.121	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	1.1 (1.21)	0.8 (1.09)	1.5 (1.73)	1.7 (1.64)	
Median	1.0	0.0	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-0.06 (0.160)	-0.53 (0.120)	0.30 (0.597)	-0.57 (0.457)	
95% CI [2]	-0.38, 0.25	-0.77, -0.29	-1.03, 1.63	-1.59, 0.44	
Difference (95% CI) in CFB [2]		-0.47 (-0.82, -0.11)		-0.87 (-1.97, 0.23)	
p-value [3]		0.010		0.110	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	1.1 (1.20)	0.8 (1.16)	1.5 (1.00)	1.6 (1.58)	
Median	1.0	0.0	1.0	1.5	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-0.02 (0.159)	-0.38 (0.120)	0.37 (0.744)	-0.59 (0.569)	
95% CI [2]	-0.33, 0.30	-0.62, -0.14	-1.29, 2.03	-1.86, 0.68	
Difference (95% CI) in CFB [2]		-0.36 (-0.71, -0.02)		-0.96 (-2.34, 0.41)	
Hedges'G (95% CI) in CFB		-0.29 (-0.62, 0.03)		-0.52 (-1.94, 0.68)	
p-value [3]		0.041		0.150	
					0.559

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	2.0 (1.15)	1.9 (1.29)	1.8 (1.26)	1.8 (1.48)	
Median	2.0	2.0	2.0	1.5	
Min, Max	0, 4	0, 4	0, 3	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	1.4 (1.27)	1.4 (1.25)	2.0 (0.82)	1.0 (1.32)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	-0.56 (0.148)	-0.62 (0.114)	0.52 (0.626)	-0.38 (0.477)	
95% CI [2]	-0.85, -0.27	-0.84, -0.39	-0.89, 1.94	-1.46, 0.70	
Difference (95% CI) in CFB [2]		-0.06 (-0.39, 0.27)		-0.90 (-2.09, 0.28)	
p-value [3]		0.720		0.119	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	118	4	9	
Mean (StdDev)	1.5 (1.15)	1.3 (1.12)	1.8 (0.50)	1.1 (1.27)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	1, 2	0, 3	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-0.45 (0.142)	-0.64 (0.107)	0.15 (0.746)	-0.41 (0.568)	
95% CI [2]	-0.73, -0.17	-0.85, -0.42	-1.54, 1.84	-1.70, 0.87	
Difference (95% CI) in CFB [2]		-0.19 (-0.50, 0.12)		-0.57 (-1.98, 0.85)	
p-value [3]		0.234		0.389	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	1.4 (1.26)	1.3 (1.18)	2.0 (0.82)	1.4 (1.51)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-0.44 (0.176)	-0.69 (0.131)	0.46 (0.516)	-0.24 (0.395)	
95% CI [2]	-0.78, -0.09	-0.95, -0.43	-0.69, 1.61	-1.12, 0.64	
Difference (95% CI) in CFB [2]		-0.25 (-0.64, 0.13)		-0.70 (-1.66, 0.25)	
p-value [3]		0.190		0.132	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	115	4	10	
Mean (StdDev)	1.4 (1.32)	1.1 (1.12)	1.8 (1.26)	1.3 (1.70)	
Median	1.0	1.0	2.0	0.5	
Min, Max	0, 4	0, 4	0, 3	0, 4	
C5D1 CFB					
n	58	109	4	10	
LS Mean (StdErr) [2]	-0.41 (0.160)	-0.79 (0.123)	0.20 (0.640)	-0.43 (0.490)	
95% CI [2]	-0.72, -0.09	-1.03, -0.54	-1.22, 1.63	-1.52, 0.67	
Difference (95% CI) in CFB [2]		-0.38 (-0.73, -0.03)		-0.63 (-1.81, 0.55)	
p-value [3]		0.035		0.264	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	1.5 (1.31)	1.0 (1.07)	2.3 (0.50)	1.3 (1.49)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	2, 3	0, 4	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-0.37 (0.165)	-1.05 (0.124)	0.70 (0.681)	-0.43 (0.521)	
95% CI [2]	-0.70, -0.05	-1.30, -0.81	-0.81, 2.22	-1.59, 0.74	
Difference (95% CI) in CFB [2]		-0.68 (-1.04, -0.31)		-1.13 (-2.39, 0.13)	
p-value [3]		<0.001		0.074	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	1.5 (1.38)	1.1 (1.21)	2.3 (0.96)	1.1 (1.29)	
Median	1.5	1.0	2.5	1.0	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-0.30 (0.185)	-0.75 (0.140)	0.80 (0.856)	-0.57 (0.655)	
95% CI [2]	-0.66, 0.07	-1.03, -0.47	-1.11, 2.70	-2.03, 0.89	
Difference (95% CI) in CFB [2]		-0.45 (-0.85, -0.05)		-1.37 (-2.95, 0.21)	
Hedges'G (95% CI) in CFB		-0.31 (-0.64, 0.01)		-0.65 (-2.10, 0.54)	
p-value [3]		0.029		0.083	
					0.334

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	2.3 (1.05)	2.2 (1.25)	2.3 (0.50)	2.4 (1.43)	
Median	2.0	2.0	2.0	2.5	
Min, Max	0, 4	0, 4	2, 3	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	1.7 (1.14)	1.6 (1.28)	1.8 (0.96)	2.1 (1.27)	
Median	2.0	1.0	1.5	2.0	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	-0.48 (0.141)	-0.61 (0.108)	-0.41 (0.978)	-0.02 (0.745)	
95% CI [2]	-0.75, -0.20	-0.82, -0.40	-2.62, 1.80	-1.71, 1.66	
Difference (95% CI) in CFB [2]		-0.13 (-0.44, 0.18)		0.39 (-1.46, 2.24)	
p-value [3]		0.397		0.644	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	118	4	9	
Mean (StdDev)	1.8 (1.16)	1.4 (1.11)	1.3 (0.50)	1.8 (1.30)	
Median	2.0	1.0	1.0	1.0	
Min, Max	0, 4	0, 4	1, 2	0, 4	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-0.43 (0.155)	-0.80 (0.118)	-0.72 (0.917)	-0.20 (0.698)	
95% CI [2]	-0.73, -0.12	-1.03, -0.57	-2.79, 1.36	-1.77, 1.38	
Difference (95% CI) in CFB [2]		-0.37 (-0.71, -0.03)		0.52 (-1.21, 2.26)	
p-value [3]		0.035		0.513	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	118	4	10	
Mean (StdDev)	1.7 (1.16)	1.4 (1.24)	2.3 (0.96)	2.0 (1.49)	
Median	2.0	1.0	2.5	2.0	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C4D1 CFB					
n	53	114	4	10	
LS Mean (StdErr) [2]	-0.61 (0.163)	-0.94 (0.121)	0.76 (1.186)	0.19 (0.908)	
95% CI [2]	-0.93, -0.29	-1.18, -0.70	-1.88, 3.40	-1.84, 2.21	
Difference (95% CI) in CFB [2]		-0.32 (-0.68, 0.03)		-0.57 (-2.77, 1.62)	
p-value [3]		0.072		0.573	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	115	4	10	
Mean (StdDev)	1.6 (1.34)	1.3 (1.19)	1.3 (0.96)	2.0 (1.33)	
Median	1.5	1.0	1.5	2.0	
Min, Max	0, 4	0, 4	0, 2	0, 4	
C5D1 CFB					
n	58	109	4	10	
LS Mean (StdErr) [2]	-0.64 (0.173)	-0.96 (0.133)	-0.76 (0.988)	-0.19 (0.757)	
95% CI [2]	-0.98, -0.30	-1.23, -0.70	-2.96, 1.44	-1.87, 1.50	
Difference (95% CI) in CFB [2]		-0.33 (-0.71, 0.06)		0.57 (-1.25, 2.40)	
p-value [3]		0.094		0.500	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	1.6 (1.26)	1.2 (1.24)	2.0 (1.41)	1.8 (1.32)	
Median	2.0	1.0	1.5	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-0.57 (0.170)	-1.03 (0.128)	1.04 (0.954)	0.24 (0.731)	
95% CI [2]	-0.91, -0.23	-1.28, -0.78	-1.09, 3.16	-1.39, 1.87	
Difference (95% CI) in CFB [2]		-0.46 (-0.84, -0.09)		-0.80 (-2.56, 0.97)	
p-value [3]		0.016		0.339	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	1.5 (1.25)	1.3 (1.23)	1.8 (0.96)	1.9 (1.37)	
Median	1.0	1.0	1.5	1.5	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-0.62 (0.177)	-0.82 (0.133)	0.22 (0.917)	-0.06 (0.702)	
95% CI [2]	-0.97, -0.27	-1.09, -0.56	-1.82, 2.27	-1.62, 1.51	
Difference (95% CI) in CFB [2]		-0.21 (-0.59, 0.18)		-0.28 (-1.98, 1.42)	
Hedges'G (95% CI) in CFB		-0.15 (-0.47, 0.17)		-0.12 (-1.44, 1.14)	
p-value [3]		0.293		0.723	
					0.748

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	2.6 (1.13)	2.6 (1.12)	3.5 (0.58)	2.9 (1.29)	
Median	3.0	3.0	3.5	3.0	
Min, Max	0, 4	0, 4	3, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	2.2 (1.10)	2.1 (1.18)	3.5 (0.58)	2.6 (1.01)	
Median	2.0	2.0	3.5	3.0	
Min, Max	0, 4	0, 4	3, 4	1, 4	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	-0.31 (0.132)	-0.49 (0.102)	-0.28 (0.419)	-0.30 (0.319)	
95% CI [2]	-0.57, -0.05	-0.69, -0.29	-1.23, 0.67	-1.03, 0.42	
Difference (95% CI) in CFB [2]		-0.18 (-0.47, 0.11)		-0.02 (-0.82, 0.77)	
p-value [3]		0.225		0.952	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	119	4	9	
Mean (StdDev)	2.2 (1.15)	2.1 (1.13)	2.5 (1.29)	2.0 (1.41)	
Median	2.0	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C3D1 CFB					
n	60	116	4	9	
LS Mean (StdErr) [2]	-0.34 (0.142)	-0.53 (0.107)	-1.70 (0.595)	-1.33 (0.453)	
95% CI [2]	-0.62, -0.06	-0.74, -0.31	-3.04, -0.35	-2.35, -0.30	
Difference (95% CI) in CFB [2]		-0.19 (-0.50, 0.12)		0.37 (-0.76, 1.50)	
p-value [3]		0.237		0.477	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	2.2 (1.10)	1.9 (1.18)	3.8 (0.50)	2.5 (0.85)	
Median	2.0	2.0	4.0	2.5	
Min, Max	0, 4	0, 4	3, 4	1, 4	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-0.33 (0.168)	-0.67 (0.124)	0.52 (0.759)	-0.13 (0.581)	
95% CI [2]	-0.66, 0.00	-0.92, -0.43	-1.17, 2.21	-1.43, 1.17	
Difference (95% CI) in CFB [2]		-0.34 (-0.71, 0.02)		-0.65 (-2.05, 0.76)	
p-value [3]		0.064		0.328	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	115	4	10	
Mean (StdDev)	2.2 (1.09)	1.9 (1.16)	3.3 (0.96)	2.5 (0.85)	
Median	2.0	2.0	3.5	2.5	
Min, Max	0, 4	0, 4	2, 4	1, 4	
C5D1 CFB					
n	58	109	4	10	
LS Mean (StdErr) [2]	-0.40 (0.170)	-0.73 (0.131)	0.59 (0.592)	0.35 (0.453)	
95% CI [2]	-0.74, -0.07	-0.99, -0.48	-0.73, 1.91	-0.66, 1.36	
Difference (95% CI) in CFB [2]		-0.33 (-0.70, 0.05)		-0.24 (-1.34, 0.85)	
p-value [3]		0.084		0.635	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	2.2 (1.21)	1.7 (1.15)	3.3 (0.96)	2.2 (1.03)	
Median	2.0	2.0	3.5	2.0	
Min, Max	0, 4	0, 4	2, 4	1, 4	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-0.28 (0.175)	-0.82 (0.132)	0.19 (0.805)	-0.30 (0.617)	
95% CI [2]	-0.63, 0.06	-1.08, -0.56	-1.61, 1.98	-1.67, 1.08	
Difference (95% CI) in CFB [2]		-0.54 (-0.92, -0.15)		-0.48 (-1.97, 1.01)	
p-value [3]		0.007		0.488	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	2.2 (1.23)	1.8 (1.15)	3.3 (0.96)	2.3 (0.95)	
Median	2.0	2.0	3.5	2.0	
Min, Max	0, 4	0, 4	2, 4	1, 4	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-0.26 (0.174)	-0.75 (0.131)	-0.41 (0.592)	-0.65 (0.453)	
95% CI [2]	-0.60, 0.08	-1.01, -0.49	-1.73, 0.91	-1.66, 0.36	
Difference (95% CI) in CFB [2]		-0.49 (-0.87, -0.12)		-0.24 (-1.34, 0.85)	
Hedges'G (95% CI) in CFB		-0.36 (-0.69, -0.04)		-0.16 (-1.49, 1.09)	
p-value [3]		0.011		0.635	
					0.808

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	2.1 (1.39)	2.0 (1.32)	2.5 (1.00)	2.6 (1.07)	
Median	2.0	2.0	3.0	3.0	
Min, Max	0, 4	0, 4	1, 3	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	1.8 (1.31)	1.6 (1.29)	2.3 (0.96)	2.4 (1.42)	
Median	2.0	2.0	2.5	2.0	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	-0.20 (0.133)	-0.39 (0.102)	-1.98 (0.626)	-1.38 (0.477)	
95% CI [2]	-0.47, 0.06	-0.59, -0.19	-3.39, -0.56	-2.46, -0.30	
Difference (95% CI) in CFB [2]		-0.19 (-0.48, 0.10)		0.60 (-0.59, 1.78)	
p-value [3]		0.206		0.283	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	62	119	4	9	
Mean (StdDev)	1.7 (1.29)	1.4 (1.23)	2.0 (0.82)	1.9 (1.27)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C3D1 CFB					
n	59	116	4	9	
LS Mean (StdErr) [2]	-0.42 (0.143)	-0.51 (0.108)	-1.50 (0.695)	-1.50 (0.529)	
95% CI [2]	-0.71, -0.14	-0.72, -0.29	-3.07, 0.07	-2.70, -0.30	
Difference (95% CI) in CFB [2]		-0.08 (-0.40, 0.23)		0.00 (-1.32, 1.32)	
p-value [3]		0.607		>0.999	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	1.7 (1.39)	1.4 (1.22)	2.0 (0.82)	2.7 (1.57)	
Median	2.0	1.0	2.0	3.0	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-0.45 (0.165)	-0.65 (0.122)	-0.63 (1.119)	-0.09 (0.856)	
95% CI [2]	-0.78, -0.12	-0.90, -0.41	-3.12, 1.86	-2.00, 1.82	
Difference (95% CI) in CFB [2]		-0.20 (-0.56, 0.15)		0.54 (-1.53, 2.61)	
p-value [3]		0.261		0.576	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	115	4	10	
Mean (StdDev)	1.6 (1.34)	1.2 (1.21)	2.3 (1.26)	1.9 (1.37)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C5D1 CFB					
n	58	109	4	10	
LS Mean (StdErr) [2]	-0.47 (0.171)	-0.77 (0.132)	-0.15 (0.711)	-0.96 (0.544)	
95% CI [2]	-0.81, -0.13	-1.03, -0.51	-1.73, 1.44	-2.18, 0.25	
Difference (95% CI) in CFB [2]		-0.30 (-0.68, 0.08)		-0.81 (-2.13, 0.50)	
p-value [3]		0.121		0.198	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	1.8 (1.40)	1.2 (1.16)	2.3 (1.50)	2.2 (1.48)	
Median	2.0	1.0	2.0	2.5	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-0.22 (0.170)	-0.80 (0.128)	-0.67 (1.036)	-0.83 (0.793)	
95% CI [2]	-0.56, 0.12	-1.05, -0.55	-2.98, 1.64	-2.60, 0.93	
Difference (95% CI) in CFB [2]		-0.58 (-0.95, -0.20)		-0.17 (-2.08, 1.75)	
p-value [3]		0.003		0.850	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	1.7 (1.36)	1.1 (1.24)	2.3 (1.50)	2.3 (1.64)	
Median	2.0	1.0	2.0	3.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-0.33 (0.159)	-0.74 (0.120)	-0.22 (1.054)	-0.44 (0.807)	
95% CI [2]	-0.64, -0.01	-0.98, -0.50	-2.57, 2.13	-2.24, 1.35	
Difference (95% CI) in CFB [2]		-0.41 (-0.76, -0.06)		-0.22 (-2.17, 1.73)	
Hedges'G (95% CI) in CFB		-0.33 (-0.66, -0.01)		-0.08 (-1.39, 1.19)	
p-value [3]		0.021		0.805	
					0.563

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	64	125	4	10	
Mean (StdDev)	2.4 (1.06)	2.4 (1.13)	2.5 (0.58)	2.9 (0.88)	
Median	2.0	2.0	2.5	3.0	
Min, Max	0, 4	0, 4	2, 3	2, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	1.8 (1.10)	1.7 (1.14)	2.5 (0.58)	2.4 (1.01)	
Median	2.0	2.0	2.5	3.0	
Min, Max	0, 4	0, 4	2, 3	1, 4	
C2D1 CFB					
n	62	123	4	9	
LS Mean (StdErr) [2]	-0.46 (0.146)	-0.63 (0.112)	-0.87 (0.971)	-1.28 (0.739)	
95% CI [2]	-0.75, -0.17	-0.85, -0.41	-3.07, 1.33	-2.96, 0.39	
Difference (95% CI) in CFB [2]		-0.17 (-0.49, 0.15)		-0.41 (-2.25, 1.42)	
p-value [3]		0.306		0.623	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	118	4	9	
Mean (StdDev)	1.9 (1.14)	1.6 (1.03)	2.0 (0.82)	2.3 (1.32)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C3D1 CFB					
n	60	115	4	9	
LS Mean (StdErr) [2]	-0.41 (0.154)	-0.75 (0.117)	-0.83 (1.186)	-1.04 (0.903)	
95% CI [2]	-0.71, -0.10	-0.98, -0.52	-3.51, 1.86	-3.09, 1.00	
Difference (95% CI) in CFB [2]		-0.34 (-0.69, -0.00)		-0.22 (-2.46, 2.03)	
p-value [3]		0.048		0.832	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	1.9 (1.15)	1.6 (1.12)	2.3 (0.50)	2.2 (1.48)	
Median	2.0	2.0	2.0	2.5	
Min, Max	0, 4	0, 4	2, 3	0, 4	
C4D1 CFB					
n	53	115	4	10	
LS Mean (StdErr) [2]	-0.50 (0.163)	-0.82 (0.121)	-0.56 (1.151)	-1.11 (0.881)	
95% CI [2]	-0.82, -0.18	-1.06, -0.58	-3.12, 2.01	-3.07, 0.85	
Difference (95% CI) in CFB [2]		-0.32 (-0.68, 0.03)		-0.56 (-2.69, 1.57)	
p-value [3]		0.073		0.574	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	115	4	10	
Mean (StdDev)	1.7 (1.18)	1.4 (1.14)	2.3 (1.26)	2.1 (1.20)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C5D1 CFB					
n	58	109	4	10	
LS Mean (StdErr) [2]	-0.65 (0.171)	-0.99 (0.132)	-0.43 (1.178)	-1.02 (0.902)	
95% CI [2]	-0.99, -0.32	-1.25, -0.73	-3.05, 2.20	-3.03, 0.99	
Difference (95% CI) in CFB [2]		-0.33 (-0.71, 0.04)		-0.59 (-2.77, 1.59)	
p-value [3]		0.083		0.558	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	1.8 (1.16)	1.4 (1.12)	2.5 (1.29)	2.2 (1.23)	
Median	2.0	1.0	2.5	2.5	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C6D1 CFB					
n	56	113	4	10	
LS Mean (StdErr) [2]	-0.51 (0.167)	-1.01 (0.125)	-0.28 (1.151)	-1.06 (0.881)	
95% CI [2]	-0.84, -0.18	-1.25, -0.76	-2.84, 2.29	-3.02, 0.91	
Difference (95% CI) in CFB [2]		-0.50 (-0.87, -0.13)		-0.78 (-2.91, 1.35)	
p-value [3]		0.008		0.435	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	1.8 (1.29)	1.4 (1.23)	2.5 (1.00)	2.1 (1.45)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	2, 4	0, 4	
C7D1 CFB					
n	56	111	4	10	
LS Mean (StdErr) [2]	-0.46 (0.197)	-0.93 (0.148)	0.26 (1.116)	-0.81 (0.854)	
95% CI [2]	-0.85, -0.07	-1.22, -0.64	-2.23, 2.75	-2.72, 1.09	
Difference (95% CI) in CFB [2]		-0.47 (-0.90, -0.04)		-1.07 (-3.14, 0.99)	
Hedges'G (95% CI) in CFB		-0.30 (-0.63, 0.02)		-0.39 (-1.77, 0.83)	
p-value [3]		0.033		0.273	
					0.679

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	63	125	4	10	
Mean (StdDev)	2.0 (1.27)	2.1 (1.19)	2.3 (1.26)	2.5 (1.08)	
Median	2.0	2.0	2.0	2.5	
Min, Max	0, 4	0, 4	1, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	1.8 (1.21)	1.7 (1.18)	2.3 (1.50)	2.2 (1.39)	
Median	2.0	2.0	2.0	3.0	
Min, Max	0, 4	0, 4	1, 4	0, 4	
C2D1 CFB					
n	61	123	4	9	
LS Mean (StdErr) [2]	-0.13 (0.143)	-0.43 (0.109)	-0.30 (1.009)	-0.17 (0.769)	
95% CI [2]	-0.41, 0.15	-0.65, -0.22	-2.59, 1.98	-1.91, 1.56	
Difference (95% CI) in CFB [2]		-0.30 (-0.61, 0.01)		0.13 (-1.78, 2.04)	
p-value [3]		0.061		0.881	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	119	4	9	
Mean (StdDev)	1.8 (1.21)	1.5 (1.11)	2.0 (0.82)	1.9 (1.27)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 3	0, 4	
C3D1 CFB					
n	59	116	4	9	
LS Mean (StdErr) [2]	-0.17 (0.141)	-0.61 (0.107)	0.65 (0.850)	0.34 (0.647)	
95% CI [2]	-0.45, 0.11	-0.82, -0.40	-1.27, 2.58	-1.13, 1.80	
Difference (95% CI) in CFB [2]		-0.43 (-0.74, -0.12)		-0.32 (-1.92, 1.29)	
p-value [3]		0.007		0.668	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	1.7 (1.25)	1.5 (1.21)	2.5 (0.58)	2.1 (1.52)	
Median	2.0	1.0	2.5	2.5	
Min, Max	0, 4	0, 4	2, 3	0, 4	
C4D1 CFB					
n	52	115	4	10	
LS Mean (StdErr) [2]	-0.27 (0.169)	-0.69 (0.125)	0.57 (0.923)	-0.02 (0.706)	
95% CI [2]	-0.61, 0.06	-0.94, -0.44	-1.48, 2.63	-1.59, 1.56	
Difference (95% CI) in CFB [2]		-0.42 (-0.79, -0.05)		-0.59 (-2.30, 1.11)	
p-value [3]		0.026		0.457	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	115	4	10	
Mean (StdDev)	1.6 (1.13)	1.4 (1.09)	1.5 (0.58)	2.3 (1.34)	
Median	2.0	1.0	1.5	3.0	
Min, Max	0, 4	0, 4	1, 2	0, 4	
C5D1 CFB					
n	57	109	4	10	
LS Mean (StdErr) [2]	-0.25 (0.161)	-0.76 (0.124)	0.52 (0.890)	0.87 (0.681)	
95% CI [2]	-0.57, 0.06	-1.00, -0.51	-1.46, 2.50	-0.65, 2.39	
Difference (95% CI) in CFB [2]		-0.51 (-0.86, -0.15)		0.35 (-1.29, 2.00)	
p-value [3]		0.006		0.644	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	1.7 (1.24)	1.3 (1.16)	1.8 (0.50)	2.3 (1.25)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 2	0, 4	
C6D1 CFB					
n	55	113	4	10	
LS Mean (StdErr) [2]	-0.22 (0.165)	-0.91 (0.123)	0.80 (0.886)	0.93 (0.679)	
95% CI [2]	-0.54, 0.11	-1.15, -0.66	-1.18, 2.77	-0.59, 2.44	
Difference (95% CI) in CFB [2]		-0.69 (-1.05, -0.32)		0.13 (-1.51, 1.77)	
p-value [3]		<0.001		0.864	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.7a
Change from Baseline in MC-QoL Individual Item Scores by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	1.7 (1.21)	1.4 (1.23)	1.8 (0.50)	2.1 (1.45)	
Median	1.5	1.0	2.0	2.0	
Min, Max	0, 4	0, 4	1, 2	0, 4	
C7D1 CFB					
n	55	111	4	10	
LS Mean (StdErr) [2]	-0.13 (0.178)	-0.63 (0.133)	0.94 (0.917)	0.89 (0.702)	
95% CI [2]	-0.48, 0.22	-0.90, -0.37	-1.10, 2.99	-0.68, 2.45	
Difference (95% CI) in CFB [2]		-0.51 (-0.89, -0.12)		-0.06 (-1.75, 1.64)	
Hedges'G (95% CI) in CFB		-0.37 (-0.70, -0.04)		-0.02 (-1.32, 1.26)	
p-value [3]		0.011		0.943	
					0.390

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-ecog-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	3.3 (0.96)	3.3 (0.95)	2.7 (1.17)	2.2 (1.10)	
Median	3.5	4.0	3.0	2.0	
Min, Max	2, 4	2, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	3.0 (0.82)	2.3 (0.95)	2.2 (1.05)	1.5 (0.93)	
Median	3.0	2.5	2.0	2.0	
Min, Max	2, 4	0, 3	0, 4	0, 4	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	-0.39 (0.687)	-0.94 (0.687)	-0.38 (0.146)	-0.59 (0.112)	
95% CI [2]	-1.92, 1.14	-2.47, 0.59	-0.67, -0.09	-0.81, -0.37	
Difference (95% CI) in CFB [2]		-0.55 (-2.50, 1.40)		-0.21 (-0.53, 0.11)	
p-value [3]		0.545		0.196	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	118	
Mean (StdDev)	2.0 (0.82)	1.9 (0.99)	2.0 (1.16)	1.5 (0.96)	
Median	2.0	2.0	2.0	1.0	
Min, Max	1, 3	0, 3	0, 4	0, 4	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	-1.32 (0.794)	-1.34 (0.794)	-0.53 (0.161)	-0.64 (0.122)	
95% CI [2]	-3.09, 0.45	-3.11, 0.43	-0.85, -0.21	-0.88, -0.40	
Difference (95% CI) in CFB [2]		-0.02 (-2.27, 2.23)		-0.11 (-0.47, 0.24)	
p-value [3]		0.985		0.527	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	2.7 (1.53)	1.4 (0.88)	2.1 (1.08)	1.4 (1.03)	
Median	3.0	1.0	2.0	1.0	
Min, Max	1, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	-0.81 (0.979)	-1.72 (0.734)	-0.47 (0.176)	-0.82 (0.132)	
95% CI [2]	-3.07, 1.45	-3.41, -0.03	-0.82, -0.12	-1.08, -0.56	
Difference (95% CI) in CFB [2]		-0.91 (-3.49, 1.68)		-0.35 (-0.73, 0.03)	
p-value [3]		0.443		0.069	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	116	
Mean (StdDev)	2.5 (1.29)	1.5 (1.31)	2.2 (1.19)	1.3 (0.97)	
Median	2.5	1.0	2.0	1.0	
Min, Max	1, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	4	8	58	110	
LS Mean (StdErr) [2]	-0.94 (0.949)	-1.40 (0.949)	-0.34 (0.173)	-0.82 (0.133)	
95% CI [2]	-3.12, 1.25	-3.59, 0.79	-0.69, -0.00	-1.08, -0.56	
Difference (95% CI) in CFB [2]		-0.46 (-3.26, 2.34)		-0.48 (-0.85, -0.10)	
p-value [3]		0.714		0.014	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	2.5 (1.29)	1.3 (1.00)	2.1 (1.22)	1.5 (1.06)	
Median	2.5	1.0	2.0	1.0	
Min, Max	1, 4	0, 3	0, 4	0, 4	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-0.74 (0.870)	-1.26 (0.870)	-0.50 (0.168)	-0.70 (0.126)	
95% CI [2]	-2.71, 1.23	-3.23, 0.71	-0.84, -0.17	-0.95, -0.45	
Difference (95% CI) in CFB [2]		-0.52 (-3.03, 1.99)		-0.19 (-0.56, 0.17)	
p-value [3]		0.649		0.299	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Itching	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	2.5 (1.29)	1.1 (0.64)	2.2 (1.17)	1.4 (1.02)	
Median	2.5	1.0	2.0	1.0	
Min, Max	1, 4	0, 2	0, 4	0, 4	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-0.62 (0.634)	-1.38 (0.634)	-0.34 (0.164)	-0.76 (0.123)	
95% CI [2]	-2.08, 0.85	-2.85, 0.08	-0.67, -0.02	-1.00, -0.51	
Difference (95% CI) in CFB [2]		-0.77 (-2.64, 1.10)		-0.41 (-0.76, -0.06)	
Hedges'G (95% CI) in CFB		-0.43 (-1.92, 0.84)		-0.32 (-0.65, 0.00)	
p-value [3]		0.370		0.022	
					0.311

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	2.5 (1.73)	2.6 (1.35)	2.5 (1.14)	2.0 (1.12)	
Median	2.5	3.0	2.5	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	3.3 (0.96)	1.2 (0.79)	2.1 (1.14)	1.4 (0.99)	
Median	3.5	1.0	2.0	1.0	
Min, Max	2, 4	0, 2	0, 4	0, 4	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	0.68 (0.794)	-1.34 (0.794)	-0.26 (0.153)	-0.49 (0.117)	
95% CI [2]	-1.09, 2.45	-3.11, 0.43	-0.57, 0.04	-0.72, -0.26	
Difference (95% CI) in CFB [2]		-2.02 (-4.27, 0.23)		-0.23 (-0.56, 0.11)	
p-value [3]		0.074		0.183	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	118	
Mean (StdDev)	1.8 (0.96)	1.5 (0.85)	2.1 (1.25)	1.4 (1.01)	
Median	1.5	1.5	2.0	1.0	
Min, Max	1, 3	0, 3	0, 4	0, 4	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	-0.97 (0.707)	-1.36 (0.707)	-0.31 (0.173)	-0.56 (0.131)	
95% CI [2]	-2.54, 0.61	-2.94, 0.21	-0.65, 0.03	-0.82, -0.31	
Difference (95% CI) in CFB [2]		-0.40 (-2.40, 1.61)		-0.25 (-0.63, 0.12)	
p-value [3]		0.669		0.186	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	2.7 (1.53)	1.3 (1.12)	2.1 (1.10)	1.3 (1.01)	
Median	3.0	1.0	2.0	1.0	
Min, Max	1, 4	0, 3	0, 4	0, 4	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	-1.12 (0.786)	-1.31 (0.589)	-0.16 (0.172)	-0.63 (0.129)	
95% CI [2]	-2.94, 0.69	-2.67, 0.05	-0.50, 0.17	-0.88, -0.38	
Difference (95% CI) in CFB [2]		-0.19 (-2.26, 1.89)		-0.47 (-0.84, -0.09)	
p-value [3]		0.840		0.014	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	116	
Mean (StdDev)	2.5 (1.29)	1.1 (0.83)	2.0 (1.30)	1.4 (1.01)	
Median	2.5	1.0	2.0	1.0	
Min, Max	1, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	4	8	58	110	
LS Mean (StdErr) [2]	-0.00 (0.719)	-1.00 (0.719)	-0.27 (0.176)	-0.55 (0.135)	
95% CI [2]	-1.66, 1.66	-2.66, 0.66	-0.62, 0.08	-0.82, -0.28	
Difference (95% CI) in CFB [2]		-1.00 (-3.12, 1.12)		-0.28 (-0.66, 0.10)	
p-value [3]		0.309		0.153	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	2.8 (1.26)	1.7 (1.00)	2.0 (1.18)	1.4 (1.08)	
Median	3.0	1.0	2.0	1.0	
Min, Max	1, 4	1, 3	0, 4	0, 4	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	0.45 (0.884)	-0.45 (0.884)	-0.21 (0.173)	-0.59 (0.129)	
95% CI [2]	-1.55, 2.44	-2.44, 1.55	-0.55, 0.14	-0.84, -0.33	
Difference (95% CI) in CFB [2]		-0.89 (-3.44, 1.66)		-0.38 (-0.76, -0.00)	
p-value [3]		0.449		0.048	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Skin Redness Swelling	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	2.3 (1.50)	0.8 (0.46)	2.1 (1.22)	1.4 (1.12)	
Median	2.0	1.0	2.0	1.0	
Min, Max	1, 4	0, 1	0, 4	0, 4	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-0.22 (0.436)	-1.45 (0.436)	-0.14 (0.183)	-0.46 (0.137)	
95% CI [2]	-1.22, 0.79	-2.45, -0.44	-0.50, 0.22	-0.73, -0.19	
Difference (95% CI) in CFB [2]		-1.23 (-2.52, 0.05)		-0.32 (-0.71, 0.07)	
Hedges'G (95% CI) in CFB		-1.00 (-2.71, 0.21)		-0.22 (-0.55, 0.10)	
p-value [3]		0.058		0.110	
					0.102

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	1.8 (0.96)	2.7 (1.34)	2.3 (1.14)	2.3 (1.07)	
Median	1.5	3.0	2.0	2.0	
Min, Max	1, 3	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	1.5 (0.58)	1.7 (1.34)	2.1 (1.09)	1.8 (1.04)	
Median	1.5	1.5	2.0	2.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	-0.36 (0.630)	-1.31 (0.630)	-0.15 (0.139)	-0.32 (0.106)	
95% CI [2]	-1.77, 1.04	-2.71, 0.10	-0.43, 0.12	-0.53, -0.11	
Difference (95% CI) in CFB [2]		-0.94 (-2.73, 0.84)		-0.16 (-0.47, 0.14)	
p-value [3]		0.267		0.288	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	118	
Mean (StdDev)	2.0 (0.82)	1.6 (1.26)	2.0 (1.02)	1.7 (1.10)	
Median	2.0	1.5	2.0	2.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	0.15 (0.732)	-1.15 (0.732)	-0.19 (0.160)	-0.41 (0.121)	
95% CI [2]	-1.48, 1.78	-2.78, 0.48	-0.51, 0.12	-0.65, -0.17	
Difference (95% CI) in CFB [2]		-1.30 (-3.38, 0.77)		-0.21 (-0.56, 0.14)	
p-value [3]		0.192		0.227	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	1.3 (0.58)	1.3 (0.87)	2.1 (1.13)	1.7 (1.03)	
Median	1.0	1.0	2.0	2.0	
Min, Max	1, 2	0, 3	0, 4	0, 4	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	-0.69 (0.804)	-1.28 (0.603)	-0.15 (0.168)	-0.49 (0.126)	
95% CI [2]	-2.54, 1.17	-2.67, 0.11	-0.48, 0.18	-0.74, -0.25	
Difference (95% CI) in CFB [2]		-0.59 (-2.72, 1.53)		-0.35 (-0.71, 0.02)	
p-value [3]		0.537		0.062	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	116	
Mean (StdDev)	1.3 (0.50)	1.3 (1.04)	2.0 (1.26)	1.7 (1.04)	
Median	1.0	1.0	2.0	2.0	
Min, Max	1, 2	0, 3	0, 4	0, 4	
C5D1 CFB					
n	4	8	58	110	
LS Mean (StdErr) [2]	-0.46 (0.723)	-1.54 (0.723)	-0.22 (0.173)	-0.45 (0.133)	
95% CI [2]	-2.13, 1.21	-3.21, 0.13	-0.56, 0.12	-0.71, -0.18	
Difference (95% CI) in CFB [2]		-1.08 (-3.21, 1.06)		-0.23 (-0.61, 0.15)	
p-value [3]		0.278		0.232	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	1.5 (1.00)	1.4 (1.33)	1.9 (1.17)	1.6 (1.09)	
Median	1.0	1.0	2.0	2.0	
Min, Max	1, 3	0, 3	0, 4	0, 4	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-0.16 (0.792)	-1.51 (0.792)	-0.25 (0.168)	-0.51 (0.126)	
95% CI [2]	-1.95, 1.63	-3.30, 0.28	-0.58, 0.08	-0.76, -0.27	
Difference (95% CI) in CFB [2]		-1.35 (-3.63, 0.94)		-0.26 (-0.63, 0.10)	
p-value [3]		0.215		0.159	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Flush Episodes

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	1.3 (0.50)	1.1 (1.13)	1.9 (1.15)	1.7 (1.08)	
Median	1.0	1.0	2.0	2.0	
Min, Max	1, 2	0, 3	0, 4	0, 4	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-0.55 (0.615)	-1.78 (0.615)	-0.24 (0.187)	-0.50 (0.140)	
95% CI [2]	-1.97, 0.87	-3.20, -0.36	-0.61, 0.13	-0.77, -0.22	
Difference (95% CI) in CFB [2]		-1.23 (-3.04, 0.58)		-0.26 (-0.66, 0.14)	
Hedges'G (95% CI) in CFB		-0.71 (-2.30, 0.53)		-0.18 (-0.50, 0.14)	
p-value [3]		0.156		0.204	
					0.341

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	1.3 (1.50)	2.2 (1.32)	2.1 (1.19)	2.1 (1.22)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	126	
Mean (StdDev)	1.3 (0.96)	1.7 (1.34)	1.7 (1.20)	1.5 (1.09)	
Median	1.5	1.5	2.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C2D1 CFB					
n	4	10	62	121	
LS Mean (StdErr) [2]	-0.02 (0.922)	-0.64 (0.922)	-0.31 (0.155)	-0.58 (0.120)	
95% CI [2]	-2.08, 2.03	-2.70, 1.41	-0.61, 0.00	-0.82, -0.35	
Difference (95% CI) in CFB [2]		-0.62 (-3.23, 1.99)		-0.28 (-0.62, 0.06)	
p-value [3]		0.607		0.105	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	118	
Mean (StdDev)	1.0 (0.82)	1.0 (0.82)	1.8 (1.31)	1.5 (1.15)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 2	0, 2	0, 4	0, 4	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	-0.42 (0.772)	-1.58 (0.772)	-0.21 (0.176)	-0.54 (0.134)	
95% CI [2]	-2.14, 1.30	-3.30, 0.14	-0.56, 0.14	-0.81, -0.28	
Difference (95% CI) in CFB [2]		-1.15 (-3.34, 1.04)		-0.33 (-0.72, 0.05)	
p-value [3]		0.268		0.092	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	1.0 (1.00)	1.3 (0.87)	1.8 (1.22)	1.4 (1.20)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 2	0, 3	0, 4	0, 4	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	-1.31 (0.814)	-1.09 (0.610)	-0.32 (0.176)	-0.59 (0.132)	
95% CI [2]	-3.19, 0.56	-2.50, 0.31	-0.66, 0.03	-0.85, -0.33	
Difference (95% CI) in CFB [2]		0.22 (-1.93, 2.37)		-0.27 (-0.65, 0.11)	
p-value [3]		0.820		0.162	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	116	
Mean (StdDev)	0.8 (0.96)	1.1 (0.99)	1.9 (1.09)	1.4 (1.17)	
Median	0.5	1.0	2.0	1.0	
Min, Max	0, 2	0, 3	0, 4	0, 4	
C5D1 CFB					
n	4	8	58	110	
LS Mean (StdErr) [2]	-0.40 (0.580)	-0.94 (0.580)	-0.15 (0.182)	-0.67 (0.139)	
95% CI [2]	-1.73, 0.94	-2.27, 0.40	-0.51, 0.21	-0.95, -0.40	
Difference (95% CI) in CFB [2]		-0.54 (-2.25, 1.17)		-0.52 (-0.92, -0.13)	
p-value [3]		0.489		0.010	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	1.0 (0.82)	1.0 (0.87)	1.8 (1.20)	1.3 (1.13)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 2	0, 3	0, 4	0, 4	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-0.19 (0.670)	-1.14 (0.670)	-0.19 (0.179)	-0.61 (0.133)	
95% CI [2]	-1.70, 1.33	-2.66, 0.37	-0.54, 0.16	-0.87, -0.35	
Difference (95% CI) in CFB [2]		-0.96 (-2.89, 0.98)		-0.42 (-0.81, -0.03)	
p-value [3]		0.292		0.034	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Diarrhea	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	1.5 (1.29)	0.8 (0.46)	1.7 (1.09)	1.4 (1.23)	
Median	1.5	1.0	2.0	1.0	
Min, Max	0, 3	0, 1	0, 4	0, 4	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	0.51 (0.807)	-1.18 (0.807)	-0.17 (0.177)	-0.49 (0.133)	
95% CI [2]	-1.35, 2.37	-3.04, 0.68	-0.52, 0.18	-0.76, -0.23	
Difference (95% CI) in CFB [2]		-1.69 (-4.07, 0.69)		-0.32 (-0.70, 0.06)	
Hedges'G (95% CI) in CFB		-0.74 (-2.35, 0.49)		-0.23 (-0.56, 0.09)	
p-value [3]		0.140		0.098	
					0.064

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	2.8 (0.96)	3.3 (0.82)	3.2 (0.90)	3.1 (0.94)	
Median	2.5	3.5	3.0	3.0	
Min, Max	2, 4	2, 4	1, 4	1, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	2.3 (0.50)	2.4 (1.65)	2.8 (0.96)	2.7 (1.03)	
Median	2.0	2.5	3.0	3.0	
Min, Max	2, 3	0, 4	1, 4	0, 4	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	-1.07 (0.507)	-1.93 (0.507)	-0.29 (0.129)	-0.43 (0.099)	
95% CI [2]	-2.19, 0.06	-3.06, -0.81	-0.54, -0.03	-0.62, -0.23	
Difference (95% CI) in CFB [2]		-0.87 (-2.30, 0.57)		-0.14 (-0.42, 0.14)	
p-value [3]		0.208		0.321	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	118	
Mean (StdDev)	2.8 (0.96)	2.4 (1.26)	2.7 (1.09)	2.4 (1.08)	
Median	2.5	2.0	3.0	2.0	
Min, Max	2, 4	1, 4	0, 4	0, 4	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	-0.24 (0.548)	-1.76 (0.548)	-0.47 (0.155)	-0.67 (0.117)	
95% CI [2]	-1.46, 0.98	-2.98, -0.54	-0.78, -0.17	-0.90, -0.43	
Difference (95% CI) in CFB [2]		-1.53 (-3.08, 0.02)		-0.19 (-0.53, 0.14)	
p-value [3]		0.053		0.258	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	2.0 (0.00)	2.4 (1.42)	2.8 (1.13)	2.4 (1.11)	
Median	2.0	2.0	3.0	2.5	
Min, Max	2, 2	0, 4	1, 4	0, 4	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	-1.44 (0.878)	-1.28 (0.659)	-0.39 (0.167)	-0.63 (0.125)	
95% CI [2]	-3.46, 0.59	-2.80, 0.24	-0.72, -0.06	-0.88, -0.39	
Difference (95% CI) in CFB [2]		0.16 (-2.16, 2.48)		-0.24 (-0.61, 0.12)	
p-value [3]		0.880		0.182	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	116	
Mean (StdDev)	2.0 (0.82)	2.3 (1.49)	2.7 (1.21)	2.3 (1.11)	
Median	2.0	2.5	3.0	2.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	4	8	58	110	
LS Mean (StdErr) [2]	-1.10 (0.740)	-1.56 (0.740)	-0.41 (0.166)	-0.72 (0.127)	
95% CI [2]	-2.81, 0.60	-3.27, 0.14	-0.74, -0.08	-0.97, -0.47	
Difference (95% CI) in CFB [2]		-0.46 (-2.64, 1.72)		-0.31 (-0.67, 0.05)	
p-value [3]		0.639		0.095	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	2.3 (0.50)	1.9 (1.45)	2.6 (1.12)	2.3 (1.13)	
Median	2.0	2.0	3.0	2.0	
Min, Max	2, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-0.83 (0.735)	-1.83 (0.735)	-0.59 (0.169)	-0.78 (0.126)	
95% CI [2]	-2.50, 0.83	-3.50, -0.17	-0.93, -0.26	-1.03, -0.54	
Difference (95% CI) in CFB [2]		-1.00 (-3.12, 1.12)		-0.19 (-0.56, 0.18)	
p-value [3]		0.314		0.307	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Fatigue	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	2.0 (0.82)	2.1 (1.36)	2.6 (1.09)	2.4 (1.05)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-1.06 (0.786)	-1.60 (0.786)	-0.52 (0.167)	-0.70 (0.125)	
95% CI [2]	-2.88, 0.75	-3.42, 0.21	-0.85, -0.19	-0.95, -0.46	
Difference (95% CI) in CFB [2]		-0.54 (-2.86, 1.78)		-0.19 (-0.54, 0.17)	
Hedges'G (95% CI) in CFB		-0.24 (-1.67, 1.07)		-0.14 (-0.47, 0.18)	
p-value [3]		0.607		0.305	
					0.997

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	1.8 (0.50)	2.2 (1.14)	2.1 (1.14)	2.1 (1.13)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	1.0 (0.00)	2.0 (1.33)	2.0 (1.08)	1.8 (1.00)	
Median	1.0	2.0	2.0	2.0	
Min, Max	1, 1	0, 4	0, 4	0, 4	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	-1.18 (0.578)	-0.82 (0.578)	-0.07 (0.129)	-0.26 (0.099)	
95% CI [2]	-2.47, 0.11	-2.11, 0.47	-0.33, 0.18	-0.46, -0.07	
Difference (95% CI) in CFB [2]		0.36 (-1.28, 2.00)		-0.19 (-0.47, 0.09)	
p-value [3]		0.636		0.183	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	118	
Mean (StdDev)	0.8 (0.96)	2.1 (0.99)	1.9 (1.07)	1.5 (0.99)	
Median	0.5	2.0	2.0	2.0	
Min, Max	0, 2	1, 4	0, 4	0, 4	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	-1.45 (0.477)	-0.88 (0.477)	-0.16 (0.154)	-0.50 (0.117)	
95% CI [2]	-2.51, -0.39	-1.95, 0.18	-0.46, 0.15	-0.73, -0.27	
Difference (95% CI) in CFB [2]		0.57 (-0.79, 1.92)		-0.34 (-0.68, -0.00)	
p-value [3]		0.373		0.049	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	1.0 (1.00)	2.3 (1.32)	1.9 (1.19)	1.6 (1.12)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 2	1, 4	0, 4	0, 4	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	-1.56 (0.711)	-0.84 (0.533)	-0.18 (0.165)	-0.37 (0.123)	
95% CI [2]	-3.20, 0.08	-2.07, 0.39	-0.51, 0.15	-0.62, -0.13	
Difference (95% CI) in CFB [2]		0.72 (-1.16, 2.60)		-0.19 (-0.55, 0.16)	
p-value [3]		0.403		0.287	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	116	
Mean (StdDev)	1.0 (1.41)	1.9 (0.83)	2.0 (1.22)	1.6 (1.16)	
Median	0.5	2.0	2.0	2.0	
Min, Max	0, 3	1, 3	0, 4	0, 4	
C5D1 CFB					
n	4	8	58	110	
LS Mean (StdErr) [2]	-0.96 (0.815)	-1.04 (0.815)	-0.22 (0.152)	-0.35 (0.117)	
95% CI [2]	-2.84, 0.92	-2.92, 0.84	-0.52, 0.08	-0.58, -0.12	
Difference (95% CI) in CFB [2]		-0.08 (-2.48, 2.33)		-0.13 (-0.46, 0.20)	
p-value [3]		0.943		0.444	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	0.5 (0.58)	1.8 (1.20)	1.9 (1.06)	1.5 (1.13)	
Median	0.5	2.0	2.0	1.0	
Min, Max	0, 1	0, 4	0, 4	0, 4	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-1.37 (0.500)	-0.96 (0.500)	-0.20 (0.155)	-0.42 (0.115)	
95% CI [2]	-2.50, -0.24	-2.09, 0.17	-0.50, 0.11	-0.65, -0.20	
Difference (95% CI) in CFB [2]		0.41 (-1.03, 1.85)		-0.23 (-0.57, 0.11)	
p-value [3]		0.533		0.183	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Headache	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	0.8 (0.96)	1.5 (0.93)	1.8 (1.08)	1.6 (1.12)	
Median	0.5	1.5	2.0	1.0	
Min, Max	0, 2	0, 3	0, 4	0, 4	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-1.08 (0.572)	-0.92 (0.572)	-0.27 (0.165)	-0.38 (0.124)	
95% CI [2]	-2.40, 0.24	-2.24, 0.40	-0.60, 0.05	-0.62, -0.13	
Difference (95% CI) in CFB [2]		0.15 (-1.53, 1.84)		-0.10 (-0.46, 0.25)	
Hedges'G (95% CI) in CFB		0.10 (-1.25, 1.48)		-0.08 (-0.40, 0.24)	
p-value [3]		0.839		0.564	
					0.558

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	1.8 (0.96)	3.6 (0.52)	2.8 (1.14)	2.6 (1.23)	
Median	1.5	4.0	3.0	3.0	
Min, Max	1, 3	3, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	126	
Mean (StdDev)	1.5 (1.00)	2.9 (1.37)	2.4 (1.07)	2.1 (1.11)	
Median	2.0	3.5	2.0	2.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C2D1 CFB					
n	4	10	62	121	
LS Mean (StdErr) [2]	-0.60 (0.670)	-1.07 (0.670)	-0.26 (0.128)	-0.38 (0.099)	
95% CI [2]	-2.09, 0.90	-2.56, 0.42	-0.51, -0.01	-0.58, -0.19	
Difference (95% CI) in CFB [2]		-0.47 (-2.37, 1.43)		-0.12 (-0.40, 0.16)	
p-value [3]		0.592		0.390	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	118	
Mean (StdDev)	1.5 (1.00)	2.6 (1.17)	2.2 (1.12)	2.0 (1.23)	
Median	2.0	2.5	2.0	2.0	
Min, Max	0, 2	1, 4	0, 4	0, 4	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	-0.51 (0.561)	-1.15 (0.561)	-0.49 (0.162)	-0.56 (0.123)	
95% CI [2]	-1.76, 0.74	-2.40, 0.10	-0.81, -0.17	-0.80, -0.31	
Difference (95% CI) in CFB [2]		-0.64 (-2.23, 0.95)		-0.06 (-0.42, 0.29)	
p-value [3]		0.390		0.726	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	2.3 (0.58)	2.9 (1.05)	2.4 (1.15)	2.1 (1.21)	
Median	2.0	3.0	2.0	2.0	
Min, Max	2, 3	1, 4	0, 4	0, 4	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	-0.56 (0.700)	-0.97 (0.525)	-0.29 (0.178)	-0.52 (0.133)	
95% CI [2]	-2.18, 1.05	-2.18, 0.24	-0.64, 0.06	-0.78, -0.25	
Difference (95% CI) in CFB [2]		-0.41 (-2.26, 1.44)		-0.23 (-0.61, 0.16)	
p-value [3]		0.626		0.247	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	116	
Mean (StdDev)	1.8 (0.50)	2.9 (0.99)	2.5 (1.13)	2.1 (1.22)	
Median	2.0	3.0	3.0	2.0	
Min, Max	1, 2	1, 4	0, 4	0, 4	
C5D1 CFB					
n	4	8	58	110	
LS Mean (StdErr) [2]	-0.23 (0.600)	-0.77 (0.600)	-0.27 (0.161)	-0.51 (0.123)	
95% CI [2]	-1.61, 1.15	-2.15, 0.61	-0.58, 0.05	-0.75, -0.27	
Difference (95% CI) in CFB [2]		-0.54 (-2.31, 1.23)		-0.24 (-0.59, 0.11)	
p-value [3]		0.503		0.171	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	1.5 (1.00)	2.4 (1.13)	2.5 (1.17)	2.0 (1.22)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 2	1, 4	0, 4	0, 4	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-0.49 (0.571)	-1.18 (0.571)	-0.21 (0.172)	-0.51 (0.128)	
95% CI [2]	-1.78, 0.81	-2.47, 0.11	-0.55, 0.12	-0.77, -0.26	
Difference (95% CI) in CFB [2]		-0.70 (-2.34, 0.95)		-0.30 (-0.67, 0.08)	
p-value [3]		0.365		0.117	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Muscle or Joint Pain

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	1.8 (1.26)	2.3 (1.16)	2.3 (1.16)	2.1 (1.20)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 3	1, 4	0, 4	0, 4	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-0.33 (0.735)	-1.33 (0.735)	-0.35 (0.160)	-0.38 (0.120)	
95% CI [2]	-2.03, 1.36	-3.03, 0.36	-0.67, -0.04	-0.62, -0.15	
Difference (95% CI) in CFB [2]		-1.00 (-3.17, 1.17)		-0.03 (-0.37, 0.31)	
Hedges'G (95% CI) in CFB		-0.48 (-1.99, 0.78)		-0.02 (-0.35, 0.30)	
p-value [3]		0.319		0.872	
					0.152

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	2.3 (1.26)	3.1 (0.99)	2.2 (1.14)	2.6 (1.10)	
Median	2.0	3.0	2.0	3.0	
Min, Max	1, 4	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	64	127	
Mean (StdDev)	2.0 (0.82)	2.6 (1.51)	2.1 (1.21)	2.0 (1.09)	
Median	2.0	3.0	2.0	2.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	4	10	61	122	
LS Mean (StdErr) [2]	-0.65 (0.509)	-1.01 (0.509)	-0.06 (0.126)	-0.48 (0.096)	
95% CI [2]	-1.79, 0.48	-2.15, 0.12	-0.31, 0.19	-0.67, -0.29	
Difference (95% CI) in CFB [2]		-0.36 (-1.80, 1.08)		-0.42 (-0.69, -0.14)	
p-value [3]		0.592		0.003	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	118	
Mean (StdDev)	2.0 (1.83)	2.2 (1.48)	2.0 (1.18)	1.8 (1.10)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	-0.55 (0.560)	-1.78 (0.560)	-0.10 (0.123)	-0.60 (0.093)	
95% CI [2]	-1.80, 0.70	-3.03, -0.53	-0.34, 0.14	-0.78, -0.41	
Difference (95% CI) in CFB [2]		-1.23 (-2.81, 0.36)		-0.50 (-0.77, -0.23)	
p-value [3]		0.116		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	1.3 (1.15)	2.1 (1.54)	2.0 (1.20)	1.9 (1.13)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	-1.31 (0.743)	-1.47 (0.558)	-0.15 (0.142)	-0.53 (0.106)	
95% CI [2]	-3.03, 0.40	-2.75, -0.18	-0.43, 0.13	-0.74, -0.32	
Difference (95% CI) in CFB [2]		-0.16 (-2.12, 1.81)		-0.38 (-0.69, -0.07)	
p-value [3]		0.859		0.016	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	116	
Mean (StdDev)	1.3 (0.96)	2.4 (1.30)	2.1 (1.24)	1.8 (1.13)	
Median	1.5	2.0	2.0	2.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C5D1 CFB					
n	4	8	58	110	
LS Mean (StdErr) [2]	-1.49 (0.546)	-1.18 (0.546)	-0.04 (0.146)	-0.59 (0.112)	
95% CI [2]	-2.75, -0.23	-2.44, 0.08	-0.32, 0.25	-0.81, -0.37	
Difference (95% CI) in CFB [2]		0.31 (-1.30, 1.92)		-0.55 (-0.87, -0.23)	
p-value [3]		0.671		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	1.0 (0.82)	2.1 (1.17)	2.0 (1.23)	1.7 (1.22)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-1.64 (0.627)	-1.36 (0.627)	-0.17 (0.150)	-0.70 (0.112)	
95% CI [2]	-3.06, -0.22	-2.78, 0.06	-0.46, 0.13	-0.92, -0.48	
Difference (95% CI) in CFB [2]		0.28 (-1.52, 2.09)		-0.53 (-0.86, -0.20)	
p-value [3]		0.732		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Difficulty Concentrating	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	2.0 (1.15)	1.8 (1.28)	2.0 (1.21)	1.7 (1.21)	
Median	2.0	1.5	2.0	2.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-0.50 (0.650)	-1.50 (0.650)	-0.11 (0.152)	-0.71 (0.114)	
95% CI [2]	-2.00, 1.00	-3.00, -0.00	-0.41, 0.19	-0.93, -0.48	
Difference (95% CI) in CFB [2]		-1.00 (-2.92, 0.92)		-0.60 (-0.92, -0.27)	
Hedges'G (95% CI) in CFB		-0.54 (-2.08, 0.71)		-0.50 (-0.83, -0.18)	
p-value [3]		0.264		<0.001	
					0.611

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	1.8 (1.26)	2.4 (1.58)	2.0 (1.40)	2.0 (1.41)	
Median	2.0	3.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	0.8 (0.50)	2.0 (1.63)	1.7 (1.40)	1.5 (1.33)	
Median	1.0	1.5	2.0	1.0	
Min, Max	0, 1	0, 4	0, 4	0, 4	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	-1.16 (0.356)	-0.18 (0.356)	-0.21 (0.197)	-0.42 (0.151)	
95% CI [2]	-1.95, -0.36	-0.97, 0.62	-0.60, 0.18	-0.72, -0.12	
Difference (95% CI) in CFB [2]		0.98 (-0.03, 1.99)		-0.21 (-0.64, 0.22)	
p-value [3]		0.056		0.338	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	117	
Mean (StdDev)	1.3 (1.26)	1.6 (1.90)	1.7 (1.33)	1.5 (1.28)	
Median	1.0	0.5	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	-0.57 (0.582)	-0.76 (0.582)	-0.19 (0.208)	-0.46 (0.157)	
95% CI [2]	-1.87, 0.72	-2.06, 0.53	-0.60, 0.22	-0.77, -0.15	
Difference (95% CI) in CFB [2]		-0.19 (-1.84, 1.46)		-0.27 (-0.72, 0.19)	
p-value [3]		0.804		0.249	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	0.7 (1.15)	1.3 (1.58)	1.9 (1.22)	1.5 (1.27)	
Median	0.0	1.0	2.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	-1.75 (0.884)	-1.25 (0.663)	-0.07 (0.217)	-0.51 (0.162)	
95% CI [2]	-3.79, 0.29	-2.78, 0.28	-0.50, 0.36	-0.83, -0.19	
Difference (95% CI) in CFB [2]		0.50 (-1.84, 2.84)		-0.44 (-0.91, 0.03)	
p-value [3]		0.635		0.065	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	59	117	
Mean (StdDev)	1.0 (0.82)	1.1 (1.46)	1.9 (1.23)	1.3 (1.27)	
Median	1.0	0.5	2.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C5D1 CFB					
n	4	8	57	111	
LS Mean (StdErr) [2]	-0.91 (0.839)	-0.76 (0.839)	-0.09 (0.203)	-0.70 (0.155)	
95% CI [2]	-2.84, 1.02	-2.69, 1.18	-0.49, 0.31	-1.01, -0.40	
Difference (95% CI) in CFB [2]		0.15 (-2.32, 2.63)		-0.61 (-1.06, -0.17)	
p-value [3]		0.890		0.007	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	1.0 (0.82)	1.4 (1.59)	1.9 (1.32)	1.4 (1.27)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-0.97 (0.497)	-0.69 (0.497)	-0.10 (0.208)	-0.59 (0.155)	
95% CI [2]	-2.10, 0.15	-1.82, 0.43	-0.51, 0.31	-0.90, -0.29	
Difference (95% CI) in CFB [2]		0.28 (-1.15, 1.72)		-0.50 (-0.95, -0.05)	
p-value [3]		0.666		0.031	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-School University Work

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	1.3 (0.96)	1.0 (1.41)	1.6 (1.33)	1.4 (1.28)	
Median	1.5	0.5	2.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-0.79 (0.636)	-0.87 (0.636)	-0.18 (0.204)	-0.56 (0.153)	
95% CI [2]	-2.26, 0.67	-2.34, 0.60	-0.58, 0.22	-0.86, -0.26	
Difference (95% CI) in CFB [2]		-0.08 (-1.95, 1.80)		-0.38 (-0.82, 0.06)	
Hedges'G (95% CI) in CFB		-0.04 (-1.42, 1.31)		-0.24 (-0.57, 0.08)	
p-value [3]		0.927		0.087	
					0.965

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	3.3 (0.96)	3.1 (0.99)	2.5 (1.26)	2.6 (1.30)	
Median	3.5	3.5	3.0	3.0	
Min, Max	2, 4	2, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	2.3 (1.26)	2.6 (1.43)	2.3 (1.23)	2.0 (1.30)	
Median	2.0	3.0	2.0	2.0	
Min, Max	1, 4	1, 4	0, 4	0, 4	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	-1.07 (0.298)	-0.93 (0.298)	-0.14 (0.164)	-0.51 (0.126)	
95% CI [2]	-1.73, -0.40	-1.60, -0.27	-0.47, 0.18	-0.76, -0.26	
Difference (95% CI) in CFB [2]		0.13 (-0.71, 0.98)		-0.37 (-0.73, -0.01)	
p-value [3]		0.735		0.043	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	117	
Mean (StdDev)	2.8 (0.96)	2.2 (1.81)	2.2 (1.23)	1.8 (1.26)	
Median	2.5	2.5	2.0	2.0	
Min, Max	2, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	-0.63 (0.493)	-1.37 (0.493)	-0.20 (0.172)	-0.69 (0.130)	
95% CI [2]	-1.73, 0.47	-2.47, -0.27	-0.54, 0.14	-0.95, -0.43	
Difference (95% CI) in CFB [2]		-0.74 (-2.13, 0.66)		-0.49 (-0.87, -0.11)	
p-value [3]		0.268		0.011	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	1.3 (1.53)	1.8 (1.48)	2.1 (1.31)	1.9 (1.34)	
Median	1.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	-2.38 (0.606)	-2.19 (0.454)	-0.24 (0.185)	-0.57 (0.138)	
95% CI [2]	-3.77, -0.98	-3.24, -1.14	-0.60, 0.13	-0.84, -0.30	
Difference (95% CI) in CFB [2]		0.19 (-1.41, 1.79)		-0.33 (-0.73, 0.07)	
p-value [3]		0.794		0.101	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	59	117	
Mean (StdDev)	1.8 (0.96)	1.5 (1.60)	2.2 (1.23)	1.7 (1.22)	
Median	1.5	1.0	2.0	2.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	4	8	57	111	
LS Mean (StdErr) [2]	-1.68 (0.746)	-1.99 (0.746)	-0.18 (0.178)	-0.81 (0.135)	
95% CI [2]	-3.40, 0.04	-3.71, -0.27	-0.53, 0.17	-1.07, -0.54	
Difference (95% CI) in CFB [2]		-0.31 (-2.51, 1.89)		-0.62 (-1.01, -0.24)	
p-value [3]		0.755		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	1.8 (0.96)	1.8 (1.79)	2.4 (1.30)	1.7 (1.26)	
Median	1.5	1.0	2.0	2.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-1.67 (0.540)	-1.67 (0.540)	0.01 (0.180)	-0.74 (0.134)	
95% CI [2]	-2.89, -0.45	-2.89, -0.45	-0.35, 0.36	-1.01, -0.48	
Difference (95% CI) in CFB [2]		0.00 (-1.56, 1.56)		-0.75 (-1.14, -0.36)	
p-value [3]		>0.999		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sport Physical Activity

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	2.3 (1.50)	1.5 (1.60)	2.1 (1.29)	1.8 (1.33)	
Median	2.0	1.0	2.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-1.24 (0.612)	-2.09 (0.612)	-0.25 (0.196)	-0.73 (0.147)	
95% CI [2]	-2.65, 0.17	-3.50, -0.68	-0.63, 0.14	-1.02, -0.44	
Difference (95% CI) in CFB [2]		-0.85 (-2.65, 0.96)		-0.49 (-0.91, -0.07)	
Hedges'G (95% CI) in CFB		-0.49 (-2.00, 0.77)		-0.32 (-0.65, 0.00)	
p-value [3]		0.311		0.023	
					0.955

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	2.3 (1.71)	3.0 (0.82)	2.3 (1.36)	2.3 (1.10)	
Median	2.5	3.0	3.0	2.0	
Min, Max	0, 4	2, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	1.8 (0.50)	2.1 (1.10)	2.1 (1.22)	1.8 (1.22)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	-0.36 (0.534)	-1.31 (0.534)	-0.15 (0.163)	-0.47 (0.125)	
95% CI [2]	-1.55, 0.83	-2.50, -0.11	-0.47, 0.17	-0.72, -0.22	
Difference (95% CI) in CFB [2]		-0.94 (-2.46, 0.57)		-0.32 (-0.68, 0.03)	
p-value [3]		0.195		0.076	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	117	
Mean (StdDev)	1.5 (0.58)	2.1 (0.99)	1.9 (1.40)	1.7 (1.14)	
Median	1.5	2.0	2.0	2.0	
Min, Max	1, 2	1, 4	0, 4	0, 4	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	-0.44 (0.499)	-0.89 (0.499)	-0.29 (0.157)	-0.58 (0.119)	
95% CI [2]	-1.55, 0.67	-2.00, 0.22	-0.60, 0.02	-0.82, -0.35	
Difference (95% CI) in CFB [2]		-0.45 (-1.87, 0.96)		-0.29 (-0.64, 0.05)	
p-value [3]		0.492		0.098	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	1.7 (0.58)	1.6 (1.33)	2.1 (1.38)	1.7 (1.22)	
Median	2.0	1.0	2.0	2.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	-1.31 (0.604)	-1.97 (0.453)	-0.22 (0.188)	-0.59 (0.140)	
95% CI [2]	-2.71, 0.08	-3.01, -0.92	-0.59, 0.15	-0.87, -0.31	
Difference (95% CI) in CFB [2]		-0.66 (-2.25, 0.94)		-0.37 (-0.78, 0.04)	
p-value [3]		0.371		0.073	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	59	117	
Mean (StdDev)	1.3 (0.96)	1.8 (1.28)	2.1 (1.34)	1.6 (1.24)	
Median	1.5	1.5	2.0	2.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C5D1 CFB					
n	4	8	57	111	
LS Mean (StdErr) [2]	-0.88 (0.533)	-1.12 (0.533)	-0.10 (0.188)	-0.76 (0.143)	
95% CI [2]	-2.11, 0.34	-2.34, 0.11	-0.48, 0.27	-1.04, -0.47	
Difference (95% CI) in CFB [2]		-0.23 (-1.80, 1.34)		-0.65 (-1.06, -0.24)	
p-value [3]		0.744		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	1.5 (0.58)	1.6 (1.42)	2.2 (1.36)	1.6 (1.23)	
Median	1.5	2.0	2.0	1.5	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-0.55 (0.729)	-1.45 (0.729)	0.07 (0.187)	-0.74 (0.140)	
95% CI [2]	-2.20, 1.09	-3.09, 0.20	-0.30, 0.44	-1.02, -0.46	
Difference (95% CI) in CFB [2]		-0.89 (-2.99, 1.21)		-0.81 (-1.22, -0.40)	
p-value [3]		0.363		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sleep

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	1.3 (0.96)	1.1 (1.36)	2.0 (1.35)	1.7 (1.27)	
Median	1.5	1.0	2.0	2.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-0.85 (0.680)	-2.15 (0.680)	-0.10 (0.188)	-0.62 (0.141)	
95% CI [2]	-2.42, 0.72	-3.72, -0.58	-0.47, 0.27	-0.89, -0.34	
Difference (95% CI) in CFB [2]		-1.31 (-3.31, 0.70)		-0.52 (-0.92, -0.11)	
Hedges'G (95% CI) in CFB		-0.68 (-2.26, 0.56)		-0.35 (-0.68, -0.03)	
p-value [3]		0.171		0.012	
					0.794

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	2.3 (1.71)	2.1 (1.73)	1.7 (1.54)	1.8 (1.46)	
Median	2.5	2.5	1.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	1.5 (1.73)	1.8 (1.93)	1.8 (1.51)	1.5 (1.40)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	-0.88 (0.700)	-0.79 (0.700)	0.07 (0.148)	-0.26 (0.113)	
95% CI [2]	-2.44, 0.68	-2.35, 0.77	-0.22, 0.36	-0.48, -0.03	
Difference (95% CI) in CFB [2]		0.09 (-1.89, 2.08)		-0.32 (-0.65, -0.00)	
p-value [3]		0.918		0.049	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	117	
Mean (StdDev)	1.5 (1.91)	1.8 (1.48)	1.5 (1.54)	1.3 (1.38)	
Median	1.0	1.5	1.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	-0.60 (0.670)	-0.07 (0.670)	-0.13 (0.156)	-0.38 (0.118)	
95% CI [2]	-2.09, 0.90	-1.56, 1.42	-0.44, 0.18	-0.61, -0.14	
Difference (95% CI) in CFB [2]		0.53 (-1.37, 2.43)		-0.24 (-0.59, 0.10)	
p-value [3]		0.549		0.160	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	2.0 (1.00)	1.0 (1.50)	1.5 (1.36)	1.4 (1.38)	
Median	2.0	0.0	1.0	1.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	-1.37 (1.057)	-1.19 (0.793)	-0.14 (0.191)	-0.35 (0.143)	
95% CI [2]	-3.81, 1.06	-3.02, 0.64	-0.51, 0.24	-0.63, -0.07	
Difference (95% CI) in CFB [2]		0.19 (-2.60, 2.98)		-0.22 (-0.63, 0.20)	
p-value [3]		0.881		0.300	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	59	116	
Mean (StdDev)	0.8 (1.50)	1.0 (1.31)	1.4 (1.39)	1.3 (1.33)	
Median	0.0	0.5	1.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C5D1 CFB					
n	4	8	57	110	
LS Mean (StdErr) [2]	-1.31 (0.699)	-0.69 (0.699)	-0.12 (0.193)	-0.46 (0.147)	
95% CI [2]	-2.92, 0.30	-2.30, 0.92	-0.50, 0.26	-0.75, -0.17	
Difference (95% CI) in CFB [2]		0.62 (-1.45, 2.68)		-0.35 (-0.77, 0.07)	
p-value [3]		0.511		0.107	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	1.0 (1.41)	1.1 (1.54)	1.4 (1.39)	1.3 (1.42)	
Median	0.5	0.0	1.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-1.31 (0.659)	-1.03 (0.659)	-0.19 (0.208)	-0.45 (0.155)	
95% CI [2]	-2.80, 0.18	-2.52, 0.47	-0.60, 0.22	-0.75, -0.14	
Difference (95% CI) in CFB [2]		0.28 (-1.62, 2.18)		-0.25 (-0.71, 0.20)	
p-value [3]		0.744		0.272	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sexual Activity	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	1.5 (1.00)	0.5 (1.07)	1.5 (1.44)	1.4 (1.41)	
Median	1.0	0.0	1.0	1.0	
Min, Max	1, 3	0, 3	0, 4	0, 4	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-0.60 (0.740)	-1.06 (0.740)	-0.04 (0.198)	-0.31 (0.149)	
95% CI [2]	-2.31, 1.10	-2.77, 0.64	-0.43, 0.35	-0.60, -0.01	
Difference (95% CI) in CFB [2]		-0.46 (-2.64, 1.72)		-0.27 (-0.70, 0.15)	
Hedges'G (95% CI) in CFB		-0.22 (-1.65, 1.09)		-0.17 (-0.50, 0.15)	
p-value [3]		0.639		0.211	
					0.760

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	2.8 (0.50)	2.9 (0.88)	2.1 (1.32)	2.3 (1.19)	
Median	3.0	3.0	2.0	2.0	
Min, Max	2, 3	2, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	2.0 (0.82)	2.3 (1.34)	1.8 (1.24)	1.8 (1.17)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	-0.99 (0.449)	-1.01 (0.449)	-0.30 (0.128)	-0.45 (0.098)	
95% CI [2]	-1.99, 0.01	-2.01, -0.01	-0.56, -0.05	-0.65, -0.26	
Difference (95% CI) in CFB [2]		-0.02 (-1.29, 1.25)		-0.15 (-0.43, 0.13)	
p-value [3]		0.974		0.288	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	117	
Mean (StdDev)	2.5 (1.29)	2.3 (1.49)	1.8 (1.29)	1.5 (1.22)	
Median	2.5	2.5	2.0	1.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	-0.24 (0.494)	-0.76 (0.494)	-0.25 (0.148)	-0.73 (0.112)	
95% CI [2]	-1.34, 0.86	-1.86, 0.34	-0.54, 0.04	-0.95, -0.51	
Difference (95% CI) in CFB [2]		-0.53 (-1.93, 0.87)		-0.48 (-0.80, -0.15)	
p-value [3]		0.420		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	1.7 (1.53)	1.6 (1.67)	1.9 (1.17)	1.5 (1.15)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	-1.44 (0.764)	-1.78 (0.573)	-0.23 (0.145)	-0.69 (0.109)	
95% CI [2]	-3.20, 0.32	-3.10, -0.46	-0.52, 0.06	-0.90, -0.47	
Difference (95% CI) in CFB [2]		-0.34 (-2.36, 1.68)		-0.45 (-0.77, -0.14)	
p-value [3]		0.705		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	59	117	
Mean (StdDev)	1.3 (0.50)	1.6 (1.51)	1.8 (1.24)	1.4 (1.21)	
Median	1.0	2.0	2.0	1.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C5D1 CFB					
n	4	8	57	111	
LS Mean (StdErr) [2]	-1.56 (0.516)	-1.10 (0.516)	-0.33 (0.159)	-0.90 (0.121)	
95% CI [2]	-2.75, -0.38	-2.29, 0.09	-0.65, -0.02	-1.13, -0.66	
Difference (95% CI) in CFB [2]		0.46 (-1.06, 1.98)		-0.56 (-0.91, -0.22)	
p-value [3]		0.504		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	1.5 (0.58)	2.1 (1.69)	2.1 (1.24)	1.4 (1.28)	
Median	1.5	2.0	2.0	1.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-1.29 (0.577)	-0.71 (0.577)	-0.02 (0.164)	-0.81 (0.123)	
95% CI [2]	-2.60, 0.01	-2.01, 0.60	-0.34, 0.31	-1.06, -0.57	
Difference (95% CI) in CFB [2]		0.59 (-1.08, 2.25)		-0.80 (-1.16, -0.44)	
p-value [3]		0.446		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Leisure Time	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	1.5 (0.58)	1.3 (1.28)	1.9 (1.40)	1.5 (1.31)	
Median	1.5	1.0	2.0	1.0	
Min, Max	1, 2	0, 3	0, 4	0, 4	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-1.26 (0.403)	-1.41 (0.403)	-0.12 (0.162)	-0.72 (0.122)	
95% CI [2]	-2.19, -0.33	-2.34, -0.48	-0.44, 0.20	-0.96, -0.48	
Difference (95% CI) in CFB [2]		-0.15 (-1.34, 1.04)		-0.60 (-0.95, -0.25)	
Hedges'G (95% CI) in CFB		-0.13 (-1.54, 1.20)		-0.47 (-0.80, -0.15)	
p-value [3]		0.773		<0.001	
					0.513

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	2.0 (1.15)	2.9 (1.20)	1.9 (1.42)	2.0 (1.28)	
Median	2.0	3.0	2.0	2.0	
Min, Max	1, 3	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	1.3 (0.96)	2.2 (1.48)	1.5 (1.21)	1.5 (1.23)	
Median	1.5	2.0	1.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	-0.96 (0.453)	-1.04 (0.453)	-0.34 (0.144)	-0.41 (0.110)	
95% CI [2]	-1.97, 0.05	-2.05, -0.03	-0.63, -0.06	-0.62, -0.19	
Difference (95% CI) in CFB [2]		-0.08 (-1.36, 1.21)		-0.07 (-0.38, 0.25)	
p-value [3]		0.898		0.683	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	117	
Mean (StdDev)	1.3 (0.50)	2.1 (1.52)	1.6 (1.31)	1.4 (1.24)	
Median	1.0	2.5	1.0	1.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	-0.69 (0.479)	-0.64 (0.479)	-0.26 (0.148)	-0.59 (0.112)	
95% CI [2]	-1.76, 0.37	-1.71, 0.43	-0.55, 0.03	-0.82, -0.37	
Difference (95% CI) in CFB [2]		0.06 (-1.30, 1.41)		-0.33 (-0.66, -0.01)	
p-value [3]		0.928		0.045	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	1.3 (0.58)	1.4 (1.74)	1.6 (1.18)	1.3 (1.20)	
Median	1.0	1.0	2.0	1.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	-2.06 (0.550)	-1.97 (0.413)	-0.33 (0.149)	-0.64 (0.112)	
95% CI [2]	-3.33, -0.79	-2.92, -1.02	-0.62, -0.03	-0.86, -0.42	
Difference (95% CI) in CFB [2]		0.09 (-1.36, 1.55)		-0.31 (-0.64, 0.01)	
p-value [3]		0.885		0.057	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	59	117	
Mean (StdDev)	1.0 (1.15)	1.4 (1.51)	1.6 (1.32)	1.3 (1.20)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C5D1 CFB					
n	4	8	57	111	
LS Mean (StdErr) [2]	-1.27 (0.353)	-1.73 (0.353)	-0.26 (0.167)	-0.75 (0.127)	
95% CI [2]	-2.08, -0.45	-2.55, -0.92	-0.58, 0.07	-1.00, -0.50	
Difference (95% CI) in CFB [2]		-0.46 (-1.50, 0.58)		-0.50 (-0.86, -0.13)	
p-value [3]		0.337		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	1.3 (1.26)	1.6 (1.67)	1.7 (1.27)	1.3 (1.29)	
Median	1.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-0.86 (0.657)	-1.47 (0.657)	-0.19 (0.164)	-0.76 (0.122)	
95% CI [2]	-2.35, 0.62	-2.96, 0.02	-0.51, 0.14	-1.00, -0.52	
Difference (95% CI) in CFB [2]		-0.61 (-2.51, 1.29)		-0.57 (-0.93, -0.21)	
p-value [3]		0.486		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Relationships

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	1.5 (1.29)	1.0 (1.20)	1.5 (1.34)	1.3 (1.33)	
Median	1.5	0.5	2.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-0.47 (0.589)	-1.86 (0.589)	-0.15 (0.164)	-0.62 (0.123)	
95% CI [2]	-1.83, 0.88	-3.22, -0.50	-0.47, 0.17	-0.87, -0.38	
Difference (95% CI) in CFB [2]		-1.38 (-3.12, 0.35)		-0.47 (-0.83, -0.12)	
Hedges'G (95% CI) in CFB		-0.83 (-2.47, 0.39)		-0.37 (-0.70, -0.05)	
p-value [3]		0.104		0.009	
					0.387

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	3.0 (0.82)	3.0 (1.15)	3.0 (0.95)	2.8 (1.03)	
Median	3.0	3.0	3.0	3.0	
Min, Max	2, 4	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	2.5 (0.58)	2.8 (0.92)	2.5 (1.09)	2.4 (1.03)	
Median	2.5	3.0	3.0	2.0	
Min, Max	2, 3	1, 4	0, 4	0, 4	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	-0.50 (0.490)	-0.16 (0.490)	-0.48 (0.130)	-0.45 (0.100)	
95% CI [2]	-1.59, 0.59	-1.26, 0.93	-0.74, -0.22	-0.64, -0.25	
Difference (95% CI) in CFB [2]		0.34 (-1.05, 1.73)		0.04 (-0.25, 0.32)	
p-value [3]		0.598		0.807	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	117	
Mean (StdDev)	2.3 (0.96)	2.2 (1.14)	2.6 (1.09)	2.2 (1.16)	
Median	2.5	2.0	3.0	2.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	-0.93 (0.380)	-1.07 (0.380)	-0.32 (0.142)	-0.53 (0.108)	
95% CI [2]	-1.78, -0.09	-1.91, -0.22	-0.60, -0.04	-0.74, -0.32	
Difference (95% CI) in CFB [2]		-0.13 (-1.21, 0.95)		-0.21 (-0.52, 0.10)	
p-value [3]		0.790		0.179	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	1.7 (0.58)	2.0 (1.32)	2.4 (1.27)	2.3 (1.22)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	-1.69 (0.440)	-1.16 (0.330)	-0.50 (0.161)	-0.43 (0.121)	
95% CI [2]	-2.70, -0.67	-1.92, -0.40	-0.82, -0.18	-0.67, -0.19	
Difference (95% CI) in CFB [2]		0.53 (-0.63, 1.69)		0.07 (-0.28, 0.41)	
p-value [3]		0.322		0.709	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	117	
Mean (StdDev)	1.8 (0.50)	2.1 (0.99)	2.5 (1.10)	2.0 (1.29)	
Median	2.0	2.0	3.0	2.0	
Min, Max	1, 2	1, 4	0, 4	0, 4	
C5D1 CFB					
n	4	8	58	111	
LS Mean (StdErr) [2]	-1.06 (0.559)	-0.60 (0.559)	-0.48 (0.173)	-0.85 (0.132)	
95% CI [2]	-2.35, 0.23	-1.89, 0.69	-0.82, -0.14	-1.12, -0.59	
Difference (95% CI) in CFB [2]		0.46 (-1.19, 2.11)		-0.37 (-0.75, 0.00)	
p-value [3]		0.537		0.053	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	2.0 (0.00)	1.8 (1.30)	2.5 (1.25)	2.1 (1.24)	
Median	2.0	1.0	3.0	2.0	
Min, Max	2, 2	0, 4	0, 4	0, 4	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-0.89 (0.436)	-1.11 (0.436)	-0.26 (0.173)	-0.60 (0.129)	
95% CI [2]	-1.88, 0.09	-2.09, -0.12	-0.60, 0.08	-0.86, -0.35	
Difference (95% CI) in CFB [2]		-0.22 (-1.47, 1.04)		-0.34 (-0.72, 0.03)	
p-value [3]		0.705		0.073	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Tired During Day

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	1.8 (0.50)	1.6 (1.41)	2.5 (1.14)	2.2 (1.14)	
Median	2.0	1.5	3.0	2.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-1.26 (0.551)	-1.41 (0.551)	-0.33 (0.168)	-0.59 (0.126)	
95% CI [2]	-2.53, 0.01	-2.68, -0.14	-0.66, 0.00	-0.84, -0.34	
Difference (95% CI) in CFB [2]		-0.15 (-1.78, 1.47)		-0.26 (-0.62, 0.10)	
Hedges'G (95% CI) in CFB		-0.10 (-1.49, 1.24)		-0.20 (-0.53, 0.12)	
p-value [3]		0.833		0.152	
					0.561

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	2.0 (1.41)	2.1 (1.37)	2.4 (1.49)	2.5 (1.20)	
Median	1.5	2.0	3.0	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	1.8 (2.06)	2.4 (1.26)	2.2 (1.22)	1.9 (1.32)	
Median	1.5	2.5	2.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	-0.37 (0.432)	-0.30 (0.432)	-0.28 (0.146)	-0.56 (0.112)	
95% CI [2]	-1.33, 0.59	-1.26, 0.67	-0.57, 0.01	-0.78, -0.34	
Difference (95% CI) in CFB [2]		0.08 (-1.15, 1.30)		-0.28 (-0.60, 0.04)	
p-value [3]		0.893		0.084	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	117	
Mean (StdDev)	1.8 (1.50)	2.0 (1.63)	2.3 (1.25)	1.8 (1.23)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	-0.50 (0.593)	-0.84 (0.593)	-0.18 (0.164)	-0.69 (0.124)	
95% CI [2]	-1.82, 0.83	-2.16, 0.49	-0.50, 0.14	-0.94, -0.45	
Difference (95% CI) in CFB [2]		-0.34 (-2.02, 1.34)		-0.51 (-0.87, -0.15)	
p-value [3]		0.662		0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	1.3 (1.53)	1.8 (1.64)	2.1 (1.35)	1.8 (1.37)	
Median	1.0	2.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	0.06 (0.403)	-0.91 (0.302)	-0.39 (0.162)	-0.62 (0.121)	
95% CI [2]	-0.87, 0.99	-1.60, -0.21	-0.71, -0.07	-0.85, -0.38	
Difference (95% CI) in CFB [2]		-0.97 (-2.03, 0.09)		-0.23 (-0.58, 0.12)	
p-value [3]		0.069		0.202	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	117	
Mean (StdDev)	2.0 (1.83)	1.6 (1.30)	2.0 (1.48)	1.7 (1.43)	
Median	2.0	1.5	2.0	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C5D1 CFB					
n	4	8	58	111	
LS Mean (StdErr) [2]	-0.12 (0.345)	-0.88 (0.345)	-0.45 (0.170)	-0.76 (0.130)	
95% CI [2]	-0.91, 0.68	-1.68, -0.09	-0.79, -0.12	-1.02, -0.50	
Difference (95% CI) in CFB [2]		-0.77 (-1.79, 0.25)		-0.31 (-0.68, 0.06)	
p-value [3]		0.120		0.100	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	1.8 (1.50)	1.6 (1.33)	2.2 (1.34)	1.6 (1.36)	
Median	2.0	1.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-0.42 (0.346)	-0.92 (0.346)	-0.14 (0.169)	-0.83 (0.126)	
95% CI [2]	-1.20, 0.37	-1.70, -0.13	-0.48, 0.19	-1.08, -0.58	
Difference (95% CI) in CFB [2]		-0.50 (-1.50, 0.50)		-0.68 (-1.05, -0.31)	
p-value [3]		0.286		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Food Choices	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	1.8 (2.06)	1.3 (1.58)	2.1 (1.43)	1.5 (1.38)	
Median	1.5	0.5	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-0.33 (0.460)	-1.33 (0.460)	-0.36 (0.181)	-0.85 (0.136)	
95% CI [2]	-1.39, 0.73	-2.39, -0.27	-0.71, -0.00	-1.11, -0.58	
Difference (95% CI) in CFB [2]		-1.00 (-2.36, 0.36)		-0.49 (-0.88, -0.10)	
Hedges'G (95% CI) in CFB		-0.77 (-2.38, 0.46)		-0.34 (-0.67, -0.02)	
p-value [3]		0.128		0.014	
					0.796

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	2.8 (0.50)	3.0 (0.94)	2.8 (1.15)	2.9 (1.00)	
Median	3.0	3.0	3.0	3.0	
Min, Max	2, 3	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	2.3 (0.50)	2.3 (1.49)	2.3 (1.15)	2.2 (1.21)	
Median	2.0	2.0	2.0	2.0	
Min, Max	2, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	-0.61 (0.330)	-1.39 (0.330)	-0.58 (0.140)	-0.70 (0.107)	
95% CI [2]	-1.35, 0.12	-2.12, -0.65	-0.85, -0.30	-0.91, -0.49	
Difference (95% CI) in CFB [2]		-0.77 (-1.71, 0.16)		-0.12 (-0.43, 0.18)	
p-value [3]		0.095		0.426	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	117	
Mean (StdDev)	2.8 (0.96)	2.4 (1.26)	2.4 (1.21)	2.0 (1.18)	
Median	2.5	2.5	2.0	2.0	
Min, Max	2, 4	0, 4	0, 4	0, 4	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	0.08 (0.447)	-0.75 (0.447)	-0.43 (0.155)	-0.91 (0.117)	
95% CI [2]	-0.91, 1.08	-1.74, 0.25	-0.73, -0.12	-1.14, -0.68	
Difference (95% CI) in CFB [2]		-0.83 (-2.10, 0.44)		-0.48 (-0.82, -0.14)	
p-value [3]		0.175		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	1.7 (0.58)	2.0 (1.12)	2.5 (1.17)	2.0 (1.24)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 2	1, 4	0, 4	0, 4	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	-1.38 (0.702)	-1.19 (0.526)	-0.36 (0.162)	-0.88 (0.121)	
95% CI [2]	-2.99, 0.24	-2.40, 0.03	-0.68, -0.04	-1.12, -0.65	
Difference (95% CI) in CFB [2]		0.19 (-1.67, 2.04)		-0.52 (-0.87, -0.17)	
p-value [3]		0.821		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	116	
Mean (StdDev)	2.0 (0.82)	2.1 (0.99)	2.3 (1.20)	1.9 (1.20)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 3	1, 4	0, 4	0, 4	
C5D1 CFB					
n	4	8	58	110	
LS Mean (StdErr) [2]	-0.96 (0.490)	-1.04 (0.490)	-0.44 (0.158)	-0.98 (0.121)	
95% CI [2]	-2.09, 0.17	-2.17, 0.09	-0.75, -0.13	-1.22, -0.74	
Difference (95% CI) in CFB [2]		-0.08 (-1.52, 1.37)		-0.54 (-0.89, -0.20)	
p-value [3]		0.905		0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	1.8 (0.50)	1.8 (1.39)	2.5 (1.17)	1.8 (1.30)	
Median	2.0	1.0	3.0	2.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-1.26 (0.618)	-1.74 (0.618)	-0.28 (0.167)	-1.05 (0.124)	
95% CI [2]	-2.66, 0.14	-3.14, -0.34	-0.61, 0.05	-1.30, -0.81	
Difference (95% CI) in CFB [2]		-0.48 (-2.26, 1.31)		-0.78 (-1.14, -0.41)	
p-value [3]		0.559		<0.0001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Less Capable	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	2.0 (1.41)	1.5 (1.31)	2.3 (1.31)	1.9 (1.29)	
Median	1.5	1.5	2.5	2.0	
Min, Max	1, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-0.78 (0.687)	-1.55 (0.687)	-0.39 (0.167)	-0.90 (0.126)	
95% CI [2]	-2.37, 0.80	-3.14, 0.03	-0.72, -0.05	-1.14, -0.65	
Difference (95% CI) in CFB [2]		-0.77 (-2.80, 1.26)		-0.51 (-0.87, -0.15)	
Hedges'G (95% CI) in CFB		-0.40 (-1.88, 0.88)		-0.39 (-0.72, -0.07)	
p-value [3]		0.407		0.006	
					0.911

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	3.5 (0.58)	3.7 (0.48)	3.0 (0.94)	3.0 (0.98)	
Median	3.5	4.0	3.0	3.0	
Min, Max	3, 4	3, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	2.5 (0.58)	2.7 (0.95)	2.6 (1.01)	2.3 (1.10)	
Median	2.5	2.0	3.0	2.0	
Min, Max	2, 3	2, 4	0, 4	0, 4	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	-1.16 (0.544)	-1.50 (0.544)	-0.36 (0.132)	-0.67 (0.101)	
95% CI [2]	-2.38, 0.05	-2.72, -0.29	-0.62, -0.10	-0.87, -0.47	
Difference (95% CI) in CFB [2]		-0.34 (-1.88, 1.20)		-0.32 (-0.60, -0.03)	
p-value [3]		0.634		0.031	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	117	
Mean (StdDev)	2.3 (0.96)	2.6 (0.97)	2.5 (1.11)	2.0 (1.19)	
Median	2.5	2.5	3.0	2.0	
Min, Max	1, 3	1, 4	0, 4	0, 4	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	-1.14 (0.630)	-1.19 (0.630)	-0.44 (0.156)	-0.92 (0.118)	
95% CI [2]	-2.54, 0.27	-2.60, 0.21	-0.75, -0.14	-1.15, -0.68	
Difference (95% CI) in CFB [2]		-0.06 (-1.84, 1.73)		-0.47 (-0.81, -0.13)	
p-value [3]		0.945		0.007	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	2.3 (1.53)	2.2 (0.83)	2.4 (1.15)	2.0 (1.17)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 4	1, 4	0, 4	0, 4	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	-1.38 (0.824)	-1.44 (0.618)	-0.57 (0.157)	-0.99 (0.117)	
95% CI [2]	-3.28, 0.53	-2.86, -0.01	-0.88, -0.26	-1.22, -0.76	
Difference (95% CI) in CFB [2]		-0.06 (-2.24, 2.12)		-0.43 (-0.77, -0.09)	
p-value [3]		0.949		0.014	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	117	
Mean (StdDev)	2.0 (1.63)	2.0 (1.20)	2.4 (1.28)	2.1 (1.20)	
Median	2.0	2.0	3.0	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C5D1 CFB					
n	4	8	58	111	
LS Mean (StdErr) [2]	-1.42 (0.893)	-1.58 (0.893)	-0.53 (0.163)	-0.96 (0.125)	
95% CI [2]	-3.48, 0.64	-3.64, 0.48	-0.85, -0.21	-1.20, -0.71	
Difference (95% CI) in CFB [2]		-0.15 (-2.79, 2.48)		-0.42 (-0.78, -0.07)	
p-value [3]		0.896		0.019	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	2.5 (1.00)	1.9 (1.27)	2.6 (1.16)	2.0 (1.27)	
Median	2.0	1.0	3.0	2.0	
Min, Max	2, 4	1, 4	0, 4	0, 4	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-1.07 (0.778)	-1.93 (0.778)	-0.41 (0.168)	-1.03 (0.126)	
95% CI [2]	-2.82, 0.69	-3.69, -0.18	-0.74, -0.08	-1.28, -0.78	
Difference (95% CI) in CFB [2]		-0.87 (-3.11, 1.37)		-0.62 (-0.99, -0.26)	
p-value [3]		0.403		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Burdened by Symptoms

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	2.5 (1.73)	1.5 (0.93)	2.3 (1.32)	2.0 (1.26)	
Median	3.0	1.5	2.5	2.0	
Min, Max	0, 4	0, 3	0, 4	0, 4	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-0.94 (0.858)	-2.40 (0.858)	-0.54 (0.169)	-0.95 (0.127)	
95% CI [2]	-2.91, 1.04	-4.38, -0.42	-0.87, -0.20	-1.20, -0.70	
Difference (95% CI) in CFB [2]		-1.46 (-3.99, 1.07)		-0.41 (-0.78, -0.05)	
Hedges'G (95% CI) in CFB		-0.60 (-2.16, 0.64)		-0.31 (-0.64, 0.01)	
p-value [3]		0.220		0.026	
					0.375

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	2.3 (1.71)	2.7 (1.49)	2.2 (1.49)	1.8 (1.44)	
Median	2.5	3.0	2.5	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	1.8 (1.26)	2.3 (1.42)	1.9 (1.44)	1.4 (1.37)	
Median	2.0	2.5	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	-0.49 (0.508)	-0.51 (0.508)	0.02 (0.165)	-0.17 (0.126)	
95% CI [2]	-1.62, 0.64	-1.64, 0.62	-0.30, 0.35	-0.42, 0.08	
Difference (95% CI) in CFB [2]		-0.02 (-1.46, 1.42)		-0.20 (-0.56, 0.16)	
p-value [3]		0.977		0.283	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	117	
Mean (StdDev)	2.0 (1.41)	1.8 (1.40)	1.9 (1.41)	1.3 (1.36)	
Median	2.5	2.5	2.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	-0.15 (0.692)	-0.85 (0.692)	-0.06 (0.182)	-0.35 (0.138)	
95% CI [2]	-1.69, 1.39	-2.39, 0.69	-0.42, 0.30	-0.62, -0.07	
Difference (95% CI) in CFB [2]		-0.70 (-2.66, 1.26)		-0.29 (-0.68, 0.11)	
p-value [3]		0.446		0.159	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	2.0 (1.73)	1.8 (1.48)	1.8 (1.27)	1.4 (1.38)	
Median	3.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	-0.12 (0.914)	-0.94 (0.686)	-0.19 (0.176)	-0.23 (0.132)	
95% CI [2]	-2.23, 1.98	-2.52, 0.64	-0.54, 0.16	-0.49, 0.03	
Difference (95% CI) in CFB [2]		-0.81 (-3.23, 1.60)		-0.04 (-0.42, 0.34)	
p-value [3]		0.460		0.830	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	117	
Mean (StdDev)	2.0 (1.41)	1.6 (1.51)	1.8 (1.36)	1.4 (1.37)	
Median	2.5	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C5D1 CFB					
n	4	8	58	111	
LS Mean (StdErr) [2]	-0.23 (0.638)	-0.77 (0.638)	-0.17 (0.194)	-0.27 (0.149)	
95% CI [2]	-1.70, 1.24	-2.24, 0.70	-0.55, 0.22	-0.56, 0.03	
Difference (95% CI) in CFB [2]		-0.54 (-2.42, 1.34)		-0.10 (-0.53, 0.32)	
p-value [3]		0.528		0.636	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	2.0 (1.41)	1.8 (1.64)	1.8 (1.46)	1.3 (1.29)	
Median	2.5	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-0.31 (0.827)	-1.03 (0.827)	-0.20 (0.198)	-0.38 (0.148)	
95% CI [2]	-2.18, 1.56	-2.90, 0.85	-0.59, 0.19	-0.67, -0.09	
Difference (95% CI) in CFB [2]		-0.72 (-3.10, 1.67)		-0.18 (-0.61, 0.25)	
p-value [3]		0.513		0.409	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Choice What to Wear

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	2.0 (1.63)	1.0 (1.41)	1.9 (1.49)	1.3 (1.30)	
Median	2.0	0.5	2.0	1.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-0.22 (0.934)	-1.45 (0.934)	0.06 (0.196)	-0.24 (0.147)	
95% CI [2]	-2.37, 1.93	-3.60, 0.70	-0.33, 0.45	-0.53, 0.05	
Difference (95% CI) in CFB [2]		-1.23 (-3.98, 1.52)		-0.30 (-0.72, 0.12)	
Hedges'G (95% CI) in CFB		-0.47 (-1.97, 0.80)		-0.20 (-0.52, 0.12)	
p-value [3]		0.333		0.159	
					0.344

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	1.8 (1.71)	1.9 (1.10)	1.7 (1.24)	1.7 (1.33)	
Median	1.5	2.0	1.5	2.0	
Min, Max	0, 4	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	1.0 (0.82)	1.7 (1.25)	1.5 (1.12)	1.3 (1.23)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	-1.09 (0.359)	-0.24 (0.359)	-0.23 (0.119)	-0.44 (0.091)	
95% CI [2]	-1.89, -0.29	-1.04, 0.56	-0.46, 0.01	-0.62, -0.26	
Difference (95% CI) in CFB [2]		0.85 (-0.17, 1.87)		-0.21 (-0.47, 0.05)	
p-value [3]		0.093		0.112	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	117	
Mean (StdDev)	1.0 (1.41)	1.3 (1.06)	1.5 (1.16)	1.0 (1.18)	
Median	0.5	1.0	1.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	-1.14 (0.521)	-0.86 (0.521)	-0.22 (0.159)	-0.69 (0.120)	
95% CI [2]	-2.30, 0.02	-2.02, 0.30	-0.54, 0.09	-0.93, -0.45	
Difference (95% CI) in CFB [2]		0.28 (-1.19, 1.76)		-0.47 (-0.82, -0.12)	
p-value [3]		0.678		0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	1.0 (1.00)	1.2 (0.83)	1.6 (1.20)	1.0 (1.18)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 2	0, 2	0, 4	0, 4	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	-0.38 (0.293)	-0.56 (0.220)	-0.24 (0.173)	-0.73 (0.129)	
95% CI [2]	-1.05, 0.30	-1.07, -0.06	-0.58, 0.10	-0.98, -0.47	
Difference (95% CI) in CFB [2]		-0.19 (-0.96, 0.59)		-0.49 (-0.86, -0.11)	
p-value [3]		0.592		0.011	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	117	
Mean (StdDev)	1.0 (0.82)	0.8 (0.71)	1.5 (1.17)	1.0 (1.20)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 2	0, 2	0, 4	0, 4	
C5D1 CFB					
n	4	8	58	111	
LS Mean (StdErr) [2]	-1.08 (0.432)	-0.92 (0.432)	-0.29 (0.158)	-0.77 (0.121)	
95% CI [2]	-2.07, -0.08	-1.92, 0.07	-0.60, 0.03	-1.01, -0.53	
Difference (95% CI) in CFB [2]		0.15 (-1.12, 1.43)		-0.48 (-0.83, -0.14)	
p-value [3]		0.788		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	1.3 (0.96)	0.9 (0.78)	1.5 (1.19)	1.1 (1.21)	
Median	1.5	1.0	1.0	1.0	
Min, Max	0, 2	0, 2	0, 4	0, 4	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-0.66 (0.436)	-0.68 (0.436)	-0.24 (0.160)	-0.68 (0.119)	
95% CI [2]	-1.64, 0.33	-1.66, 0.31	-0.56, 0.08	-0.92, -0.45	
Difference (95% CI) in CFB [2]		-0.02 (-1.28, 1.24)		-0.45 (-0.79, -0.10)	
p-value [3]		0.970		0.013	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Allergic Reaction	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	1.3 (1.26)	0.5 (0.53)	1.3 (1.12)	1.0 (1.15)	
Median	1.0	0.5	1.0	1.0	
Min, Max	0, 3	0, 1	0, 4	0, 4	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-0.81 (0.548)	-1.19 (0.548)	-0.36 (0.159)	-0.63 (0.120)	
95% CI [2]	-2.07, 0.46	-2.46, 0.07	-0.67, -0.04	-0.87, -0.40	
Difference (95% CI) in CFB [2]		-0.38 (-2.00, 1.23)		-0.27 (-0.62, 0.07)	
Hedges'G (95% CI) in CFB		-0.25 (-1.68, 1.06)		-0.22 (-0.55, 0.10)	
p-value [3]		0.598		0.116	
					0.661

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	1.3 (0.96)	1.9 (1.29)	1.2 (1.30)	1.3 (1.47)	
Median	1.5	2.0	1.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	1.0 (1.15)	1.0 (1.25)	1.2 (1.35)	1.2 (1.36)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	0.13 (0.493)	-0.13 (0.493)	-0.02 (0.144)	-0.14 (0.110)	
95% CI [2]	-0.97, 1.23	-1.23, 0.97	-0.30, 0.26	-0.36, 0.08	
Difference (95% CI) in CFB [2]		-0.26 (-1.66, 1.13)		-0.12 (-0.43, 0.19)	
p-value [3]		0.682		0.453	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	117	
Mean (StdDev)	0.8 (0.96)	0.8 (1.23)	1.0 (1.20)	0.9 (1.19)	
Median	0.5	0.5	1.0	0.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	-0.37 (0.493)	-0.63 (0.493)	-0.11 (0.161)	-0.34 (0.122)	
95% CI [2]	-1.47, 0.73	-1.73, 0.47	-0.42, 0.21	-0.58, -0.10	
Difference (95% CI) in CFB [2]		-0.26 (-1.66, 1.13)		-0.24 (-0.59, 0.12)	
p-value [3]		0.682		0.188	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	1.0 (1.00)	0.2 (0.44)	1.3 (1.28)	1.0 (1.22)	
Median	1.0	0.0	1.0	1.0	
Min, Max	0, 2	0, 1	0, 4	0, 4	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	0.19 (0.617)	-0.84 (0.463)	-0.06 (0.166)	-0.47 (0.124)	
95% CI [2]	-1.24, 1.61	-1.91, 0.22	-0.38, 0.27	-0.71, -0.22	
Difference (95% CI) in CFB [2]		-1.03 (-2.66, 0.60)		-0.41 (-0.77, -0.05)	
p-value [3]		0.183		0.025	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	117	
Mean (StdDev)	1.5 (1.29)	0.3 (0.46)	1.1 (1.26)	0.9 (1.21)	
Median	1.5	0.0	1.0	0.0	
Min, Max	0, 3	0, 1	0, 4	0, 4	
C5D1 CFB					
n	4	8	58	111	
LS Mean (StdErr) [2]	0.45 (0.487)	-0.78 (0.487)	-0.10 (0.152)	-0.49 (0.117)	
95% CI [2]	-0.67, 1.57	-1.90, 0.34	-0.40, 0.20	-0.73, -0.26	
Difference (95% CI) in CFB [2]		-1.23 (-2.67, 0.20)		-0.40 (-0.73, -0.06)	
p-value [3]		0.083		0.019	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	0.8 (0.96)	0.2 (0.44)	1.2 (1.25)	0.9 (1.18)	
Median	0.5	0.0	1.0	0.0	
Min, Max	0, 2	0, 1	0, 4	0, 4	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-0.26 (0.508)	-0.74 (0.508)	-0.06 (0.158)	-0.50 (0.118)	
95% CI [2]	-1.41, 0.89	-1.89, 0.41	-0.37, 0.25	-0.73, -0.27	
Difference (95% CI) in CFB [2]		-0.48 (-1.94, 0.99)		-0.44 (-0.79, -0.10)	
p-value [3]		0.479		0.012	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Wrong Treatment

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	0.8 (0.96)	0.0 (0.00)	1.1 (1.20)	0.9 (1.23)	
Median	0.5	0.0	1.0	0.0	
Min, Max	0, 2	0, 0	0, 4	0, 4	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-0.32 (0.546)	-1.01 (0.546)	0.00 (0.157)	-0.34 (0.118)	
95% CI [2]	-1.58, 0.94	-2.27, 0.25	-0.31, 0.31	-0.57, -0.10	
Difference (95% CI) in CFB [2]		-0.69 (-2.30, 0.92)		-0.34 (-0.68, -0.00)	
Hedges'G (95% CI) in CFB		-0.45 (-1.95, 0.82)		-0.28 (-0.60, 0.04)	
p-value [3]		0.351		0.048	
					0.305

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	2.0 (1.41)	2.5 (1.35)	2.0 (1.15)	1.8 (1.28)	
Median	2.5	2.5	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	1.5 (1.29)	1.6 (1.43)	1.5 (1.26)	1.3 (1.24)	
Median	1.5	1.5	1.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	-0.42 (0.807)	-0.58 (0.807)	-0.53 (0.144)	-0.60 (0.110)	
95% CI [2]	-2.22, 1.37	-2.37, 1.22	-0.81, -0.24	-0.82, -0.39	
Difference (95% CI) in CFB [2]		-0.15 (-2.44, 2.14)		-0.07 (-0.39, 0.24)	
p-value [3]		0.886		0.640	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	117	
Mean (StdDev)	1.8 (1.26)	1.6 (1.07)	1.5 (1.12)	1.2 (1.13)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	-0.14 (0.714)	-0.19 (0.714)	-0.46 (0.140)	-0.62 (0.106)	
95% CI [2]	-1.73, 1.45	-1.79, 1.40	-0.74, -0.18	-0.83, -0.41	
Difference (95% CI) in CFB [2]		-0.06 (-2.08, 1.97)		-0.16 (-0.47, 0.15)	
p-value [3]		0.952		0.301	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	1.3 (1.53)	1.1 (1.05)	1.5 (1.24)	1.3 (1.22)	
Median	1.0	1.0	1.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	-0.88 (0.786)	-0.69 (0.589)	-0.40 (0.169)	-0.63 (0.127)	
95% CI [2]	-2.69, 0.94	-2.05, 0.67	-0.73, -0.06	-0.88, -0.38	
Difference (95% CI) in CFB [2]		0.19 (-1.89, 2.26)		-0.23 (-0.60, 0.14)	
p-value [3]		0.840		0.215	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	117	
Mean (StdDev)	1.5 (1.00)	0.6 (0.92)	1.4 (1.33)	1.1 (1.18)	
Median	2.0	0.0	1.0	1.0	
Min, Max	0, 2	0, 2	0, 4	0, 4	
C5D1 CFB					
n	4	8	58	111	
LS Mean (StdErr) [2]	-0.28 (0.575)	-1.05 (0.575)	-0.41 (0.158)	-0.72 (0.121)	
95% CI [2]	-1.61, 1.04	-2.38, 0.28	-0.72, -0.10	-0.96, -0.48	
Difference (95% CI) in CFB [2]		-0.77 (-2.47, 0.93)		-0.31 (-0.66, 0.03)	
p-value [3]		0.326		0.073	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	1.5 (1.29)	0.4 (0.73)	1.5 (1.30)	1.0 (1.12)	
Median	1.5	0.0	1.0	1.0	
Min, Max	0, 3	0, 2	0, 4	0, 4	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-0.36 (0.801)	-1.64 (0.801)	-0.35 (0.160)	-0.96 (0.119)	
95% CI [2]	-2.17, 1.45	-3.45, 0.17	-0.66, -0.03	-1.19, -0.72	
Difference (95% CI) in CFB [2]		-1.28 (-3.59, 1.03)		-0.61 (-0.96, -0.26)	
p-value [3]		0.241		<0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Public Uncomfortable	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	1.3 (0.96)	0.4 (0.52)	1.6 (1.39)	1.1 (1.23)	
Median	1.5	0.0	2.0	1.0	
Min, Max	0, 2	0, 1	0, 4	0, 4	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-0.54 (0.672)	-1.46 (0.672)	-0.24 (0.182)	-0.67 (0.137)	
95% CI [2]	-2.09, 1.01	-3.01, 0.09	-0.60, 0.12	-0.94, -0.40	
Difference (95% CI) in CFB [2]		-0.92 (-2.91, 1.06)		-0.43 (-0.82, -0.04)	
Hedges'G (95% CI) in CFB		-0.49 (-2.00, 0.78)		-0.30 (-0.63, 0.02)	
p-value [3]		0.314		0.032	
					0.247

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	2.5 (0.58)	2.6 (1.17)	2.3 (1.05)	2.2 (1.27)	
Median	2.5	2.5	2.0	2.0	
Min, Max	2, 3	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	1.3 (0.50)	1.6 (1.17)	1.7 (1.15)	1.6 (1.29)	
Median	1.0	1.0	2.0	2.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	-1.36 (0.584)	-1.31 (0.584)	-0.42 (0.144)	-0.53 (0.110)	
95% CI [2]	-2.66, -0.06	-2.61, -0.00	-0.70, -0.13	-0.75, -0.32	
Difference (95% CI) in CFB [2]		0.06 (-1.60, 1.71)		-0.12 (-0.43, 0.20)	
p-value [3]		0.941		0.464	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	117	
Mean (StdDev)	1.8 (1.50)	1.5 (1.18)	1.7 (1.12)	1.4 (1.13)	
Median	2.0	1.5	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	-0.85 (0.839)	-1.15 (0.839)	-0.44 (0.153)	-0.74 (0.116)	
95% CI [2]	-2.72, 1.02	-3.02, 0.72	-0.74, -0.13	-0.96, -0.51	
Difference (95% CI) in CFB [2]		-0.30 (-2.68, 2.08)		-0.30 (-0.64, 0.04)	
p-value [3]		0.783		0.080	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	119	
Mean (StdDev)	1.3 (1.15)	0.9 (0.78)	1.8 (1.15)	1.5 (1.29)	
Median	2.0	1.0	2.0	1.0	
Min, Max	0, 2	0, 2	0, 4	0, 4	
C4D1 CFB					
n	3	9	54	115	
LS Mean (StdErr) [2]	-1.69 (0.851)	-1.41 (0.638)	-0.53 (0.167)	-0.84 (0.125)	
95% CI [2]	-3.65, 0.28	-2.88, 0.07	-0.86, -0.20	-1.08, -0.59	
Difference (95% CI) in CFB [2]		0.28 (-1.97, 2.53)		-0.31 (-0.67, 0.05)	
p-value [3]		0.780		0.093	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	117	
Mean (StdDev)	1.8 (1.50)	1.1 (0.99)	1.6 (1.32)	1.3 (1.23)	
Median	2.0	1.0	1.5	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C5D1 CFB					
n	4	8	58	111	
LS Mean (StdErr) [2]	-0.94 (0.619)	-1.40 (0.619)	-0.64 (0.177)	-0.88 (0.135)	
95% CI [2]	-2.36, 0.49	-2.83, 0.03	-0.99, -0.29	-1.14, -0.61	
Difference (95% CI) in CFB [2]		-0.46 (-2.29, 1.36)		-0.24 (-0.62, 0.15)	
p-value [3]		0.576		0.228	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	1.3 (1.50)	1.1 (1.27)	1.7 (1.25)	1.3 (1.26)	
Median	1.0	1.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-1.34 (0.663)	-1.32 (0.663)	-0.49 (0.176)	-0.96 (0.131)	
95% CI [2]	-2.84, 0.16	-2.82, 0.18	-0.84, -0.14	-1.21, -0.70	
Difference (95% CI) in CFB [2]		0.02 (-1.89, 1.93)		-0.47 (-0.85, -0.08)	
p-value [3]		0.980		0.017	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Worsening Mastocytosis	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	2.0 (1.41)	0.6 (0.52)	1.5 (1.22)	1.4 (1.27)	
Median	2.5	1.0	1.0	1.0	
Min, Max	0, 3	0, 1	0, 4	0, 4	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-0.44 (0.559)	-1.90 (0.559)	-0.63 (0.180)	-0.72 (0.135)	
95% CI [2]	-1.73, 0.85	-3.19, -0.61	-0.99, -0.27	-0.98, -0.45	
Difference (95% CI) in CFB [2]		-1.46 (-3.11, 0.19)		-0.09 (-0.47, 0.30)	
Hedges'G (95% CI) in CFB		-0.92 (-2.60, 0.29)		-0.06 (-0.38, 0.26)	
p-value [3]		0.075		0.657	
					0.082

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	2.5 (0.58)	3.0 (0.94)	2.6 (1.15)	2.6 (1.14)	
Median	2.5	3.0	3.0	3.0	
Min, Max	2, 3	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	2.0 (0.82)	2.5 (1.18)	2.3 (1.13)	2.1 (1.17)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 3	1, 4	0, 4	0, 4	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	-0.63 (0.574)	-1.04 (0.574)	-0.27 (0.131)	-0.47 (0.100)	
95% CI [2]	-1.91, 0.65	-2.32, 0.24	-0.53, -0.01	-0.67, -0.27	
Difference (95% CI) in CFB [2]		-0.42 (-2.04, 1.21)		-0.20 (-0.48, 0.09)	
p-value [3]		0.582		0.175	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	118	
Mean (StdDev)	2.5 (1.00)	2.5 (1.08)	2.2 (1.16)	2.0 (1.15)	
Median	2.0	2.5	2.0	2.0	
Min, Max	2, 4	1, 4	0, 4	0, 4	
C3D1 CFB					
n	4	10	60	115	
LS Mean (StdErr) [2]	0.22 (0.598)	-0.22 (0.598)	-0.43 (0.141)	-0.57 (0.107)	
95% CI [2]	-1.12, 1.55	-1.55, 1.12	-0.71, -0.15	-0.79, -0.36	
Difference (95% CI) in CFB [2]		-0.43 (-2.13, 1.26)		-0.15 (-0.46, 0.16)	
p-value [3]		0.581		0.352	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	1.7 (0.58)	2.3 (0.87)	2.4 (1.14)	1.9 (1.18)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 2	1, 4	0, 4	0, 4	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	-1.25 (0.919)	-0.88 (0.689)	-0.23 (0.165)	-0.65 (0.123)	
95% CI [2]	-3.37, 0.87	-2.46, 0.71	-0.56, 0.09	-0.89, -0.41	
Difference (95% CI) in CFB [2]		0.37 (-2.05, 2.80)		-0.41 (-0.77, -0.06)	
p-value [3]		0.731		0.023	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	117	
Mean (StdDev)	1.8 (0.50)	2.0 (1.20)	2.3 (1.13)	1.9 (1.15)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 2	0, 4	0, 4	0, 4	
C5D1 CFB					
n	4	8	58	111	
LS Mean (StdErr) [2]	-0.63 (0.755)	-0.71 (0.755)	-0.37 (0.168)	-0.69 (0.128)	
95% CI [2]	-2.37, 1.11	-2.45, 1.04	-0.70, -0.04	-0.94, -0.43	
Difference (95% CI) in CFB [2]		-0.08 (-2.30, 2.15)		-0.32 (-0.68, 0.05)	
p-value [3]		0.938		0.089	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	2.0 (0.82)	1.9 (1.17)	2.3 (1.25)	1.8 (1.15)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-0.56 (0.807)	-1.11 (0.807)	-0.26 (0.174)	-0.79 (0.130)	
95% CI [2]	-2.39, 1.26	-2.93, 0.72	-0.60, 0.09	-1.05, -0.54	
Difference (95% CI) in CFB [2]		-0.54 (-2.87, 1.78)		-0.53 (-0.91, -0.16)	
p-value [3]		0.610		0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Lack of Motivation	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	1.5 (1.29)	1.3 (0.89)	2.3 (1.23)	1.8 (1.15)	
Median	1.5	1.5	2.0	2.0	
Min, Max	0, 3	0, 2	0, 4	0, 4	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-0.95 (0.855)	-1.72 (0.855)	-0.21 (0.166)	-0.69 (0.125)	
95% CI [2]	-2.92, 1.02	-3.69, 0.25	-0.54, 0.12	-0.94, -0.45	
Difference (95% CI) in CFB [2]		-0.77 (-3.29, 1.75)		-0.48 (-0.84, -0.13)	
Hedges'G (95% CI) in CFB		-0.32 (-1.77, 0.98)		-0.37 (-0.70, -0.05)	
p-value [3]		0.502		0.008	
					0.938

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	1.8 (1.26)	2.3 (1.49)	2.2 (1.38)	2.0 (1.30)	
Median	2.0	3.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	1.8 (1.26)	1.7 (1.42)	1.9 (1.31)	1.6 (1.31)	
Median	2.0	2.0	2.0	2.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	0.08 (0.506)	-0.75 (0.506)	-0.26 (0.137)	-0.39 (0.105)	
95% CI [2]	-1.05, 1.21	-1.88, 0.38	-0.53, 0.01	-0.60, -0.19	
Difference (95% CI) in CFB [2]		-0.83 (-2.26, 0.60)		-0.13 (-0.43, 0.17)	
p-value [3]		0.226		0.399	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	62	118	
Mean (StdDev)	1.5 (1.29)	1.6 (1.26)	1.7 (1.28)	1.4 (1.24)	
Median	1.5	2.0	2.0	1.0	
Min, Max	0, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	4	10	59	115	
LS Mean (StdErr) [2]	-0.33 (0.790)	-1.01 (0.790)	-0.47 (0.141)	-0.52 (0.107)	
95% CI [2]	-2.09, 1.43	-2.77, 0.75	-0.74, -0.19	-0.73, -0.31	
Difference (95% CI) in CFB [2]		-0.68 (-2.92, 1.56)		-0.06 (-0.37, 0.25)	
p-value [3]		0.515		0.722	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	1.3 (1.15)	1.4 (1.24)	1.7 (1.37)	1.5 (1.30)	
Median	2.0	2.0	2.0	1.0	
Min, Max	0, 2	0, 3	0, 4	0, 4	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	-0.19 (1.011)	-0.78 (0.758)	-0.48 (0.169)	-0.61 (0.126)	
95% CI [2]	-2.52, 2.14	-2.53, 0.97	-0.81, -0.15	-0.86, -0.36	
Difference (95% CI) in CFB [2]		-0.59 (-3.26, 2.08)		-0.13 (-0.49, 0.23)	
p-value [3]		0.622		0.481	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	117	
Mean (StdDev)	1.8 (1.50)	0.9 (0.99)	1.7 (1.34)	1.3 (1.25)	
Median	2.0	0.5	2.0	1.0	
Min, Max	0, 3	0, 2	0, 4	0, 4	
C5D1 CFB					
n	4	8	58	111	
LS Mean (StdErr) [2]	-0.09 (0.718)	-1.24 (0.718)	-0.51 (0.175)	-0.75 (0.134)	
95% CI [2]	-1.75, 1.57	-2.90, 0.41	-0.85, -0.16	-1.02, -0.49	
Difference (95% CI) in CFB [2]		-1.15 (-3.27, 0.96)		-0.25 (-0.63, 0.13)	
p-value [3]		0.244		0.204	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	2.0 (1.41)	1.2 (1.09)	1.8 (1.41)	1.3 (1.23)	
Median	2.5	1.0	2.0	1.0	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	0.41 (0.518)	-0.74 (0.518)	-0.30 (0.176)	-0.80 (0.132)	
95% CI [2]	-0.76, 1.58	-1.92, 0.43	-0.65, 0.05	-1.06, -0.54	
Difference (95% CI) in CFB [2]		-1.15 (-2.65, 0.34)		-0.50 (-0.88, -0.11)	
p-value [3]		0.115		0.011	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Alone with Illness

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	1.8 (1.26)	0.9 (0.99)	1.8 (1.38)	1.2 (1.33)	
Median	2.0	0.5	2.0	1.0	
Min, Max	0, 3	0, 2	0, 4	0, 4	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	0.15 (0.663)	-1.15 (0.663)	-0.38 (0.165)	-0.70 (0.124)	
95% CI [2]	-1.37, 1.68	-2.68, 0.37	-0.71, -0.06	-0.94, -0.45	
Difference (95% CI) in CFB [2]		-1.31 (-3.26, 0.65)		-0.31 (-0.67, 0.04)	
Hedges'G (95% CI) in CFB		-0.70 (-2.29, 0.54)		-0.24 (-0.57, 0.08)	
p-value [3]		0.162		0.085	
					0.217

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	64	125	
Mean (StdDev)	2.3 (0.50)	2.8 (1.23)	2.4 (1.06)	2.4 (1.11)	
Median	2.0	3.0	2.0	2.0	
Min, Max	2, 3	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	1.3 (0.96)	2.0 (1.33)	1.9 (1.09)	1.8 (1.14)	
Median	1.5	2.0	2.0	2.0	
Min, Max	0, 2	0, 4	0, 4	0, 4	
C2D1 CFB					
n	4	10	62	122	
LS Mean (StdErr) [2]	-1.10 (0.542)	-1.23 (0.542)	-0.41 (0.150)	-0.62 (0.115)	
95% CI [2]	-2.31, 0.11	-2.44, -0.02	-0.70, -0.11	-0.85, -0.40	
Difference (95% CI) in CFB [2]		-0.13 (-1.67, 1.40)		-0.21 (-0.54, 0.11)	
p-value [3]		0.852		0.196	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	117	
Mean (StdDev)	2.3 (0.96)	1.6 (1.17)	1.9 (1.13)	1.7 (1.06)	
Median	2.5	1.0	2.0	2.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	4	10	60	114	
LS Mean (StdErr) [2]	-0.11 (0.764)	-1.56 (0.764)	-0.45 (0.157)	-0.72 (0.119)	
95% CI [2]	-1.81, 1.60	-3.26, 0.14	-0.76, -0.14	-0.95, -0.48	
Difference (95% CI) in CFB [2]		-1.45 (-3.62, 0.71)		-0.26 (-0.61, 0.08)	
p-value [3]		0.166		0.137	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	2.0 (1.00)	1.3 (1.12)	1.9 (1.13)	1.7 (1.16)	
Median	2.0	1.0	2.0	2.0	
Min, Max	1, 3	0, 3	0, 4	0, 4	
C4D1 CFB					
n	3	9	54	116	
LS Mean (StdErr) [2]	-0.38 (0.931)	-1.69 (0.698)	-0.50 (0.166)	-0.78 (0.124)	
95% CI [2]	-2.52, 1.77	-3.30, -0.08	-0.83, -0.17	-1.03, -0.54	
Difference (95% CI) in CFB [2]		-1.31 (-3.77, 1.15)		-0.28 (-0.64, 0.08)	
p-value [3]		0.254		0.127	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	117	
Mean (StdDev)	1.5 (1.29)	1.0 (0.76)	1.8 (1.18)	1.5 (1.17)	
Median	1.5	1.0	2.0	1.0	
Min, Max	0, 3	0, 2	0, 4	0, 4	
C5D1 CFB					
n	4	8	58	111	
LS Mean (StdErr) [2]	-0.91 (0.880)	-1.76 (0.880)	-0.62 (0.173)	-0.93 (0.132)	
95% CI [2]	-2.94, 1.12	-3.78, 0.27	-0.96, -0.28	-1.20, -0.67	
Difference (95% CI) in CFB [2]		-0.85 (-3.44, 1.75)		-0.31 (-0.69, 0.06)	
p-value [3]		0.474		0.103	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	1.8 (1.26)	1.2 (0.83)	1.9 (1.18)	1.5 (1.17)	
Median	2.0	1.0	2.0	1.5	
Min, Max	0, 3	0, 3	0, 4	0, 4	
C6D1 CFB					
n	4	9	56	114	
LS Mean (StdErr) [2]	-0.60 (0.630)	-1.73 (0.630)	-0.49 (0.174)	-0.96 (0.130)	
95% CI [2]	-2.03, 0.82	-3.16, -0.31	-0.84, -0.15	-1.22, -0.71	
Difference (95% CI) in CFB [2]		-1.13 (-2.95, 0.69)		-0.47 (-0.85, -0.09)	
p-value [3]		0.193		0.015	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Concerned	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	1.8 (1.26)	0.6 (0.74)	1.8 (1.29)	1.5 (1.27)	
Median	2.0	0.5	2.0	2.0	
Min, Max	0, 3	0, 2	0, 4	0, 4	
C7D1 CFB					
n	4	8	56	113	
LS Mean (StdErr) [2]	-0.54 (0.800)	-2.46 (0.800)	-0.44 (0.197)	-0.83 (0.148)	
95% CI [2]	-2.38, 1.31	-4.31, -0.62	-0.83, -0.05	-1.12, -0.54	
Difference (95% CI) in CFB [2]		-1.92 (-4.28, 0.44)		-0.39 (-0.81, 0.03)	
Hedges'G (95% CI) in CFB		-0.85 (-2.50, 0.37)		-0.25 (-0.58, 0.07)	
p-value [3]		0.097		0.071	
					0.105

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	63	125	
Mean (StdDev)	2.0 (0.82)	2.6 (1.07)	2.0 (1.29)	2.1 (1.19)	
Median	2.0	2.0	2.0	2.0	
Min, Max	1, 3	1, 4	0, 4	0, 4	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	2.0 (0.82)	1.8 (1.14)	1.8 (1.24)	1.8 (1.20)	
Median	2.0	1.0	2.0	2.0	
Min, Max	1, 3	1, 4	0, 4	0, 4	
C2D1 CFB					
n	4	10	61	122	
LS Mean (StdErr) [2]	-0.01 (0.609)	-0.65 (0.609)	-0.14 (0.147)	-0.39 (0.112)	
95% CI [2]	-1.37, 1.34	-2.01, 0.70	-0.43, 0.15	-0.61, -0.17	
Difference (95% CI) in CFB [2]		-0.64 (-2.37, 1.08)		-0.25 (-0.57, 0.07)	
p-value [3]		0.427		0.129	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	118	
Mean (StdDev)	1.8 (0.96)	1.7 (1.16)	1.8 (1.21)	1.6 (1.12)	
Median	1.5	1.5	2.0	2.0	
Min, Max	1, 3	0, 4	0, 4	0, 4	
C3D1 CFB					
n	4	10	59	115	
LS Mean (StdErr) [2]	-0.23 (0.701)	-0.77 (0.701)	-0.16 (0.142)	-0.56 (0.107)	
95% CI [2]	-1.79, 1.34	-2.34, 0.79	-0.44, 0.12	-0.77, -0.35	
Difference (95% CI) in CFB [2]		-0.55 (-2.53, 1.44)		-0.40 (-0.71, -0.09)	
p-value [3]		0.553		0.012	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	2.0 (1.00)	1.8 (1.09)	1.7 (1.25)	1.5 (1.26)	
Median	2.0	2.0	2.0	1.0	
Min, Max	1, 3	0, 3	0, 4	0, 4	
C4D1 CFB					
n	3	9	53	116	
LS Mean (StdErr) [2]	-0.56 (1.182)	-0.72 (0.886)	-0.22 (0.166)	-0.66 (0.124)	
95% CI [2]	-3.29, 2.16	-2.76, 1.33	-0.54, 0.11	-0.90, -0.41	
Difference (95% CI) in CFB [2]		-0.16 (-3.28, 2.97)		-0.44 (-0.80, -0.08)	
p-value [3]		0.911		0.017	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	117	
Mean (StdDev)	1.8 (0.96)	1.3 (1.04)	1.6 (1.12)	1.4 (1.14)	
Median	1.5	1.0	2.0	1.0	
Min, Max	1, 3	0, 3	0, 4	0, 4	
C5D1 CFB					
n	4	8	57	111	
LS Mean (StdErr) [2]	-0.19 (1.003)	-0.81 (1.003)	-0.28 (0.159)	-0.66 (0.121)	
95% CI [2]	-2.50, 2.12	-3.12, 1.50	-0.59, 0.03	-0.90, -0.42	
Difference (95% CI) in CFB [2]		-0.62 (-3.57, 2.34)		-0.38 (-0.73, -0.04)	
p-value [3]		0.644		0.030	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	2.3 (0.96)	1.2 (0.83)	1.7 (1.22)	1.4 (1.22)	
Median	2.5	1.0	2.0	1.0	
Min, Max	1, 3	0, 3	0, 4	0, 4	
C6D1 CFB					
n	4	9	55	114	
LS Mean (StdErr) [2]	0.14 (0.608)	-1.47 (0.608)	-0.26 (0.171)	-0.81 (0.127)	
95% CI [2]	-1.24, 1.51	-2.85, -0.10	-0.60, 0.08	-1.06, -0.56	
Difference (95% CI) in CFB [2]		-1.61 (-3.36, 0.15)		-0.55 (-0.92, -0.17)	
p-value [3]		0.068		0.004	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.12.1.8a
Change from Baseline in MC-QoL Individual Item Scores by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

MCQOL-Sad

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	1.8 (0.96)	1.3 (0.89)	1.7 (1.19)	1.5 (1.27)	
Median	1.5	1.0	2.0	2.0	
Min, Max	1, 3	0, 3	0, 4	0, 4	
C7D1 CFB					
n	4	8	55	113	
LS Mean (StdErr) [2]	-0.26 (0.718)	-1.41 (0.718)	-0.11 (0.180)	-0.53 (0.135)	
95% CI [2]	-1.91, 1.40	-3.07, 0.25	-0.47, 0.24	-0.80, -0.26	
Difference (95% CI) in CFB [2]		-1.15 (-3.27, 0.96)		-0.42 (-0.81, -0.03)	
Hedges'G (95% CI) in CFB		-0.57 (-2.11, 0.68)		-0.30 (-0.63, 0.03)	
p-value [3]		0.244		0.035	
					0.417

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.3
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-ind-g-itt-thpy-a.sas Date: 16:03/07AUG2023

Table 35.2.8.4.1.1a
Proportion of Patients with MC-QoL Total Score Change from Baseline <= -15 Points by C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients MC-QoL Total Scores Change from Baseline <= -15 Points	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	31/ 71 (43.7) (31.9, 56.0)	93/141 (66.0) (57.5, 73.7)	2.61 (1.39, 4.97) 0.001	1.54 (1.15, 2.08) 0.004	0.23 (0.09, 0.37) 0.001	
Age Group (Years)						0.234
< 65	28/ 60 (46.7) (33.7, 60.0)	86/132 (65.2) (56.4, 73.2)	2.25 (1.14, 4.41) 0.011	1.43 (1.05, 1.93) 0.022	0.20 (0.05, 0.35) 0.011	
>= 65	3/ 11 (27.3) (6.0, 61.0)	7/ 9 (77.8) (40.0, 97.2)	13.33 (0.96, 649.08) 0.020	5.11 (0.85, 30.91) 0.076	0.60 (0.21, 0.99) 0.003	
Sex						0.811
Male	6/ 17 (35.3) (14.2, 61.7)	25/ 41 (61.0) (44.5, 75.8)	2.93 (0.80, 11.63) 0.069	1.76 (0.88, 3.53) 0.110	0.27 (-0.01, 0.54) 0.056	
Female	25/ 54 (46.3) (32.6, 60.4)	68/100 (68.0) (57.9, 77.0)	2.48 (1.22, 5.43) 0.007	1.50 (1.08, 2.08) 0.016	0.23 (0.06, 0.39) 0.007	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-totscore-resp-itt-a.sas Date: 15:59/14AUG2025

Table 35.2.8.4.1.1a
Proportion of Patients with MC-QoL Total Score Change from Baseline <= -15 Points by C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients MC-QoL Total Scores Change from Baseline <= -15 Points	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Region						0.510
North America	13/ 33 (39.4) (22.9, 57.9)	40/ 60 (66.7) (53.3, 78.3)	4.00 (1.35, 12.11) 0.005	1.79 (1.12, 2.87) 0.015	0.30 (0.10, 0.49) 0.003	
Europe	18/ 38 (47.4) (31.0, 64.2)	53/ 81 (65.4) (54.0, 75.7)	2.09 (0.89, 4.95) 0.062	1.38 (0.95, 2.01) 0.089	0.18 (-0.01, 0.37) 0.062	
Country						0.902
BEL	1/ 1 (100.0) (2.5, 100.0)	1/ 3 (33.3) (0.8, 90.6)	0.00 (0.00, 19.00) 0.317	0.00 (NE, NE) NE	-1.00 (-1.00, -1.00) NE	
CAN	2/ 5 (40.0) (5.3, 85.3)	6/ 8 (75.0) (34.9, 96.8)	NE (0.41, NE) 0.090	2.56 (0.66, 9.84) 0.173	0.56 (0.15, 0.97) 0.008	
CHE	1/ 1 (100.0) (2.5, 100.0)	1/ 2 (50.0) (1.3, 98.7)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DEU	8/ 15 (53.3) (26.6, 78.7)	10/ 19 (52.6) (28.9, 75.6)	0.92 (0.20, 4.07) 0.897	0.96 (0.47, 1.95) >0.999	-0.02 (-0.39, 0.34) 0.898	
DNK	0/0	1/ 1 (100.0) (2.5, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-totscore-resp-itt-a.sas Date: 15:59/14AUG2025

Table 35.2.8.4.1.1a
Proportion of Patients with MC-QoL Total Score Change from Baseline <= -15 Points by C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients MC-QoL Total Scores Change from Baseline <= -15 Points	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
ESP	0/ 3 (0.0) (0.0, 70.8)	10/ 14 (71.4) (41.9, 91.6)	NE (0.89, NE) 0.031	NE (NE, NE) NE	0.73 (0.46, 1.00) <0.0001	
FRA	5/ 6 (83.3) (35.9, 99.6)	8/ 11 (72.7) (39.0, 94.0)	5.00 (0.03, 469.25) 0.378	1.20 (0.72, 2.02) 0.480	0.16 (-0.20, 0.51) 0.389	
GBR	2/ 5 (40.0) (5.3, 85.3)	8/ 11 (72.7) (39.0, 94.0)	3.30 (0.24, 64.00) 0.246	1.92 (0.47, 7.78) 0.361	0.34 (-0.24, 0.91) 0.249	
ITA	0/0	3/ 4 (75.0) (19.4, 99.4)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
NLD	0/ 3 (0.0) (0.0, 70.8)	8/ 9 (88.9) (51.8, 99.7)	NE (0.32, NE) 0.114	NE (NE, NE) NE	0.67 (0.13, 1.00) 0.014	
NOR	1/ 3 (33.3) (0.8, 90.6)	1/ 5 (20.0) (0.5, 71.6)	0.60 (0.01, 45.78) 0.695	0.60 (0.05, 7.92) >0.999	-0.14 (-0.90, 0.62) 0.713	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-totscore-resp-itt-a.sas Date: 15:59/14AUG2025

Table 35.2.8.4.1.1a
Proportion of Patients with MC-QoL Total Score Change from Baseline <= -15 Points by C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients MC-QoL Total Scores Change from Baseline <= -15 Points	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
SWE	0/ 1 (0.0) (0.0, 97.5)	2/ 2 (100.0) (15.8, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
USA	11/ 28 (39.3) (21.5, 59.4)	34/ 52 (65.4) (50.9, 78.0)	3.95 (1.21, 13.16) 0.011	1.80 (1.07, 3.01) 0.026	0.30 (0.08, 0.51) 0.006	
Baseline ISM Status						0.271
Moderate	8/ 26 (30.8) (14.3, 51.8)	33/ 52 (63.5) (49.0, 76.4)	4.53 (1.40, 14.30) 0.004	2.15 (1.16, 3.98) 0.015	0.34 (0.13, 0.56) 0.002	
Severe	23/ 45 (51.1) (35.8, 66.3)	59/ 87 (67.8) (56.9, 77.4)	1.98 (0.90, 4.49) 0.061	1.33 (0.96, 1.86) 0.090	0.17 (-0.01, 0.35) 0.065	
Baseline Serum Tryptase (ng/mL)						0.131
< 20	8/ 15 (53.3) (26.6, 78.7)	15/ 28 (53.6) (33.9, 72.5)	1.21 (0.27, 5.47) 0.780	1.09 (0.58, 2.05) 0.790	0.04 (-0.27, 0.35) 0.777	
>= 20	23/ 56 (41.1) (28.1, 55.0)	78/113 (69.0) (59.6, 77.4)	3.24 (1.57, 6.61) <0.001	1.68 (1.20, 2.36) 0.002	0.28 (0.13, 0.44) <0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-totscore-resp-itt-a.sas Date: 15:59/14AUG2025

Table 35.2.8.4.1.1a
Proportion of Patients with MC-QoL Total Score Change from Baseline <= -15 Points by C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients MC-QoL Total Scores Change from Baseline <= -15 Points	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.690
0 or 1	30/ 67 (44.8) (32.6, 57.4)	87/131 (66.4) (57.6, 74.4)	2.56 (1.34, 5.01) 0.002	1.52 (1.12, 2.05) 0.007	0.23 (0.08, 0.37) 0.002	
2+	1/ 4 (25.0) (0.6, 80.6)	6/ 10 (60.0) (26.2, 87.8)	NE (0.35, NE) 0.142	2.83 (0.54, 14.96) 0.220	0.41 (0.05, 0.77) 0.027	
Prior TKI therapy						0.294
Yes	3/ 4 (75.0) (19.4, 99.4)	7/ 10 (70.0) (34.8, 93.3)	0.94 (0.01, 84.88) 0.951	0.97 (0.22, 4.29) >0.999	-0.02 (-0.73, 0.69) 0.959	
No	28/ 67 (41.8) (29.8, 54.5)	86/131 (65.6) (56.9, 73.7)	2.76 (1.45, 5.43) <0.001	1.61 (1.17, 2.21) 0.003	0.25 (0.11, 0.39) <0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-totscore-resp-itt-a.sas Date: 15:59/14AUG2025

Table 35.2.8.4.2.1a
Proportion of Patients with MC-QoL Symptoms Domain Score Change from Baseline <= -15 Points by C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients MC-QoL Symptoms Domain Score Change from Baseline <= -15 Points	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	38/ 71 (53.5) (41.3, 65.5)	102/141 (72.3) (64.2, 79.5)	2.45 (1.26, 4.68) 0.004	1.37 (1.08, 1.74) 0.010	0.20 (0.06, 0.33) 0.004	
Age Group (Years)						0.088
< 65	35/ 60 (58.3) (44.9, 70.9)	94/132 (71.2) (62.7, 78.8)	1.91 (0.93, 3.82) 0.055	1.24 (0.98, 1.57) 0.076	0.14 (-0.00, 0.28) 0.058	
>= 65	3/ 11 (27.3) (6.0, 61.0)	8/ 9 (88.9) (51.8, 99.7)	26.20 (1.35, 1061.18) 0.007	3.90 (1.20, 12.67) 0.024	0.68 (0.33, 1.00) <0.001	
Sex						0.796
Male	10/ 17 (58.8) (32.9, 81.6)	30/ 41 (73.2) (57.1, 85.8)	2.34 (0.53, 10.41) 0.196	1.28 (0.84, 1.95) 0.250	0.16 (-0.09, 0.42) 0.207	
Female	28/ 54 (51.9) (37.8, 65.7)	72/100 (72.0) (62.1, 80.5)	2.41 (1.13, 5.10) 0.013	1.39 (1.04, 1.85) 0.024	0.20 (0.04, 0.36) 0.013	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-symptom-resp-itt-a.sas Date: 15:59/14AUG2025

Table 35.2.8.4.2.1a
Proportion of Patients with MC-QoL Symptoms Domain Score Change from Baseline <= -15 Points by C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients MC-QoL Symptoms Domain Score Change from Baseline <= -15 Points	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Region						0.955
North America	17/ 33 (51.5) (33.5, 69.2)	42/ 60 (70.0) (56.8, 81.2)	2.45 (0.85, 6.74) 0.065	1.38 (0.95, 2.00) 0.090	0.19 (-0.01, 0.40) 0.061	
Europe	21/ 38 (55.3) (38.3, 71.4)	60/ 81 (74.1) (63.1, 83.2)	2.37 (0.95, 5.64) 0.039	1.35 (0.98, 1.84) 0.063	0.19 (0.01, 0.37) 0.042	
Country						0.789
BEL	0/ 1 (0.0) (0.0, 97.5)	1/ 3 (33.3) (0.8, 90.6)	NE (NE, NE) NE	NE (NE, NE) NE	0.00 (0.00, 0.00) NE	
CAN	1/ 5 (20.0) (0.5, 71.6)	7/ 8 (87.5) (47.3, 99.7)	NE (0.75, NE) 0.050	7.67 (0.50, 117.71) 0.144	0.80 (0.55, 1.00) <0.0001	
CHE	1/ 1 (100.0) (2.5, 100.0)	1/ 2 (50.0) (1.3, 98.7)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DEU	9/ 15 (60.0) (32.3, 83.7)	11/ 19 (57.9) (33.5, 79.7)	0.90 (0.19, 4.15) 0.867	0.95 (0.53, 1.72) >0.999	-0.03 (-0.39, 0.33) 0.868	
DNK	0/0	1/ 1 (100.0) (2.5, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-symptom-resp-itt-a.sas Date: 15:59/14AUG2025

Table 35.2.8.4.2.1a
Proportion of Patients with MC-QoL Symptoms Domain Score Change from Baseline <= -15 Points by C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients MC-QoL Symptoms Domain Score Change from Baseline <= -15 Points	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
ESP	1/ 3 (33.3) (0.8, 90.6)	12/ 14 (85.7) (57.2, 98.2)	10.50 (0.42, 706.81) 0.042	2.58 (0.56, 11.84) 0.222	0.58 (-0.06, 1.00) 0.074	
FRA	4/ 6 (66.7) (22.3, 95.7)	9/ 11 (81.8) (48.2, 97.7)	NE (0.43, NE) 0.079	1.56 (0.81, 2.99) 0.180	0.36 (-0.03, 0.75) 0.071	
GBR	3/ 5 (60.0) (14.7, 94.7)	11/ 11 (100.0) (71.5, 100.0)	NE (0.67, NE) 0.034	1.81 (0.77, 4.24) 0.170	0.45 (0.03, 0.87) 0.035	
ITA	0/0	2/ 4 (50.0) (6.8, 93.2)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
NLD	0/ 3 (0.0) (0.0, 70.8)	7/ 9 (77.8) (40.0, 97.2)	NE (0.32, NE) 0.114	NE (NE, NE) NE	0.67 (0.13, 1.00) 0.014	
NOR	2/ 3 (66.7) (9.4, 99.2)	3/ 5 (60.0) (14.7, 94.7)	0.50 (0.00, 78.17) 0.739	0.84 (0.35, 2.06) >0.999	-0.11 (-0.66, 0.45) 0.705	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-symptom-resp-itt-a.sas Date: 15:59/14AUG2025

Table 35.2.8.4.2.1a
Proportion of Patients with MC-QoL Symptoms Domain Score Change from Baseline <= -15 Points by C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients MC-QoL Symptoms Domain Score Change from Baseline <= -15 Points	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
SWE	1/ 1 (100.0) (2.5, 100.0)	2/ 2 (100.0) (15.8, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
USA	16/ 28 (57.1) (37.2, 75.5)	35/ 52 (67.3) (52.9, 79.7)	1.78 (0.57, 5.54) 0.269	1.22 (0.83, 1.79) 0.305	0.12 (-0.09, 0.34) 0.269	
Baseline ISM Status						0.306
Moderate	10/ 26 (38.5) (20.2, 59.4)	35/ 52 (67.3) (52.9, 79.7)	4.01 (1.24, 12.37) 0.009	1.83 (1.09, 3.08) 0.023	0.31 (0.09, 0.53) 0.005	
Severe	28/ 45 (62.2) (46.5, 76.2)	66/ 87 (75.9) (65.5, 84.4)	1.85 (0.79, 4.32) 0.119	1.21 (0.93, 1.57) 0.150	0.13 (-0.04, 0.30) 0.129	
Baseline Serum Tryptase (ng/mL)						0.557
< 20	7/ 15 (46.7) (21.3, 73.4)	16/ 28 (57.1) (37.2, 75.5)	1.92 (0.42, 9.01) 0.350	1.34 (0.69, 2.60) 0.382	0.15 (-0.15, 0.45) 0.328	
>= 20	31/ 56 (55.4) (41.5, 68.7)	86/113 (76.1) (67.2, 83.6)	2.63 (1.24, 5.48) 0.006	1.38 (1.07, 1.78) 0.014	0.21 (0.06, 0.36) 0.007	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-symptom-resp-itt-a.sas Date: 15:59/14AUG2025

Table 35.2.8.4.2.1a
Proportion of Patients with MC-QoL Symptoms Domain Score Change from Baseline <= -15 Points by C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients MC-QoL Symptoms Domain Score Change from Baseline <= -15 Points	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.367
0 or 1	35/ 67 (52.2) (39.7, 64.6)	95/131 (72.5) (64.0, 80.0)	2.63 (1.32, 5.18) 0.003	1.41 (1.10, 1.82) 0.008	0.21 (0.07, 0.35) 0.003	
2+	3/ 4 (75.0) (19.4, 99.4)	7/ 10 (70.0) (34.8, 93.3)	0.80 (0.01, 17.82) 0.851	0.93 (0.45, 1.90) >0.999	-0.06 (-0.64, 0.53) 0.853	
Prior TKI therapy						0.794
Yes	2/ 4 (50.0) (6.8, 93.2)	7/ 10 (70.0) (34.8, 93.3)	2.67 (0.12, 163.73) 0.448	1.52 (0.55, 4.22) 0.424	0.28 (-0.43, 0.99) 0.433	
No	36/ 67 (53.7) (41.1, 66.0)	95/131 (72.5) (64.0, 80.0)	2.49 (1.26, 4.94) 0.004	1.38 (1.08, 1.77) 0.011	0.20 (0.06, 0.34) 0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-symptom-resp-itt-a.sas Date: 15:59/14AUG2025

Table 35.2.8.4.3.1a
Proportion of Patients with MC-QoL Social Domain Score Change from Baseline <= -15 Points by C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients MC-QoL Social Domain Score Change from Baseline <= -15 Points	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	35/ 71 (49.3) (37.2, 61.4)	97/141 (68.8) (60.5, 76.3)	2.41 (1.27, 4.54) 0.004	1.42 (1.09, 1.84) 0.008	0.21 (0.07, 0.34) 0.004	
Age Group (Years)						0.153
< 65	31/ 60 (51.7) (38.4, 64.8)	89/132 (67.4) (58.7, 75.3)	2.05 (1.03, 4.03) 0.026	1.33 (1.01, 1.74) 0.042	0.17 (0.02, 0.32) 0.027	
>= 65	4/ 11 (36.4) (10.9, 69.2)	8/ 9 (88.9) (51.8, 99.7)	NE (2.12, NE) 0.007	4.19 (1.15, 15.22) 0.030	0.70 (0.45, 0.95) <0.0001	
Sex						0.752
Male	8/ 17 (47.1) (23.0, 72.2)	26/ 41 (63.4) (46.9, 77.9)	2.24 (0.56, 8.24) 0.211	1.38 (0.81, 2.36) 0.241	0.18 (-0.09, 0.44) 0.190	
Female	27/ 54 (50.0) (36.1, 63.9)	71/100 (71.0) (61.1, 79.6)	2.59 (1.24, 5.65) 0.006	1.45 (1.08, 1.95) 0.013	0.22 (0.06, 0.39) 0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-social-resp-itt-a.sas Date: 15:59/14AUG2025

Table 35.2.8.4.3.1a
Proportion of Patients with MC-QoL Social Domain Score Change from Baseline <= -15 Points by C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients MC-QoL Social Domain Score Change from Baseline <= -15 Points	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Region						0.657
North America	15/ 33 (45.5) (28.1, 63.6)	41/ 60 (68.3) (55.0, 79.7)	3.60 (1.18, 9.99) 0.011	1.59 (1.07, 2.37) 0.021	0.27 (0.07, 0.46) 0.008	
Europe	20/ 38 (52.6) (35.8, 69.0)	56/ 81 (69.1) (57.9, 78.9)	2.01 (0.84, 4.70) 0.085	1.31 (0.94, 1.84) 0.112	0.16 (-0.02, 0.35) 0.087	
Country						0.939
BEL	1/ 1 (100.0) (2.5, 100.0)	3/ 3 (100.0) (29.2, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
CAN	3/ 5 (60.0) (14.7, 94.7)	6/ 8 (75.0) (34.9, 96.8)	NE (0.26, NE) 0.152	1.92 (0.63, 5.83) 0.252	0.44 (0.04, 0.84) 0.029	
CHE	1/ 1 (100.0) (2.5, 100.0)	1/ 2 (50.0) (1.3, 98.7)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DEU	9/ 15 (60.0) (32.3, 83.7)	11/ 19 (57.9) (33.5, 79.7)	0.75 (0.13, 3.87) 0.713	0.90 (0.52, 1.55) >0.999	-0.06 (-0.38, 0.26) 0.698	
DNK	0/0	1/ 1 (100.0) (2.5, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-social-resp-itt-a.sas Date: 15:59/14AUG2025

Table 35.2.8.4.3.1a
Proportion of Patients with MC-QoL Social Domain Score Change from Baseline <= -15 Points by C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients MC-QoL Social Domain Score Change from Baseline <= -15 Points	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
ESP	0/ 3 (0.0) (0.0, 70.8)	9/ 14 (64.3) (35.1, 87.2)	NE (0.70, NE) 0.056	NE (NE, NE) NE	0.67 (0.39, 0.94) <0.0001	
FRA	5/ 6 (83.3) (35.9, 99.6)	9/ 11 (81.8) (48.2, 97.7)	NE (0.16, NE) 0.083	1.31 (0.77, 2.21) 0.319	0.23 (-0.10, 0.57) 0.173	
GBR	2/ 5 (40.0) (5.3, 85.3)	8/ 11 (72.7) (39.0, 94.0)	3.30 (0.24, 64.00) 0.246	1.92 (0.47, 7.78) 0.361	0.34 (-0.24, 0.91) 0.249	
ITA	0/0	3/ 4 (75.0) (19.4, 99.4)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
NLD	1/ 3 (33.3) (0.8, 90.6)	7/ 9 (77.8) (40.0, 97.2)	1.00 (0.01, 117.33) >0.999	1.00 (0.10, 9.61) >0.999	0.00 (-0.75, 0.75) >0.999	
NOR	1/ 3 (33.3) (0.8, 90.6)	2/ 5 (40.0) (5.3, 85.3)	1.20 (0.05, 98.03) 0.861	1.20 (0.13, 11.37) 0.874	0.07 (-0.82, 0.97) 0.876	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-social-resp-itt-a.sas Date: 15:59/14AUG2025

Table 35.2.8.4.3.1a
Proportion of Patients with MC-QoL Social Domain Score Change from Baseline <= -15 Points by C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients MC-QoL Social Domain Score Change from Baseline <= -15 Points	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
SWE	0/ 1 (0.0) (0.0, 97.5)	2/ 2 (100.0) (15.8, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
USA	12/ 28 (42.9) (24.5, 62.8)	35/ 52 (67.3) (52.9, 79.7)	3.90 (1.16, 12.29) 0.013	1.67 (1.07, 2.63) 0.025	0.28 (0.07, 0.49) 0.008	
Baseline ISM Status						0.314
Moderate	10/ 26 (38.5) (20.2, 59.4)	35/ 52 (67.3) (52.9, 79.7)	3.83 (1.24, 12.37) 0.009	1.81 (1.08, 3.04) 0.023	0.31 (0.09, 0.53) 0.006	
Severe	25/ 45 (55.6) (40.0, 70.4)	61/ 87 (70.1) (59.4, 79.5)	1.87 (0.82, 4.17) 0.102	1.26 (0.94, 1.69) 0.125	0.14 (-0.03, 0.32) 0.104	
Baseline Serum Tryptase (ng/mL)						0.524
< 20	7/ 15 (46.7) (21.3, 73.4)	16/ 28 (57.1) (37.2, 75.5)	1.92 (0.42, 9.01) 0.350	1.33 (0.72, 2.48) 0.366	0.15 (-0.15, 0.45) 0.330	
>= 20	28/ 56 (50.0) (36.3, 63.7)	81/113 (71.7) (62.4, 79.8)	2.56 (1.24, 5.25) 0.005	1.44 (1.08, 1.91) 0.013	0.22 (0.06, 0.38) 0.006	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-social-resp-itt-a.sas Date: 15:59/14AUG2025

Table 35.2.8.4.3.1a
Proportion of Patients with MC-QoL Social Domain Score Change from Baseline <= -15 Points by C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients MC-QoL Social Domain Score Change from Baseline <= -15 Points	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.394
0 or 1	32/ 67 (47.8) (35.4, 60.3)	90/131 (68.7) (60.0, 76.5)	2.57 (1.32, 4.95) 0.003	1.46 (1.11, 1.93) 0.007	0.22 (0.08, 0.36) 0.002	
2+	3/ 4 (75.0) (19.4, 99.4)	7/ 10 (70.0) (34.8, 93.3)	1.00 (0.01, 104.37) >0.999	1.00 (0.54, 1.85) >0.999	0.00 (-0.44, 0.44) >0.999	
Prior TKI therapy						0.972
Yes	4/ 4 (100.0) (39.8, 100.0)	7/ 10 (70.0) (34.8, 93.3)	0.00 (0.00, 3.87) 0.152	0.58 (0.26, 1.30) >0.999	-0.42 (-0.73, -0.10) 0.009	
No	31/ 67 (46.3) (34.0, 58.9)	90/131 (68.7) (60.0, 76.5)	2.70 (1.39, 5.24) 0.001	1.51 (1.14, 2.01) 0.004	0.24 (0.09, 0.38) 0.001	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-social-resp-itt-a.sas Date: 15:59/14AUG2025

Table 35.2.8.4.4.1a
Proportion of Patients with MC-QoL Emotions Domain Score Change from Baseline <= -15 Points by C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients MC-QoL Emotions Domain Score Change from Baseline <= -15 Points	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	37/ 71 (52.1) (39.9, 64.1)	101/141 (71.6) (63.4, 78.9)	2.56 (1.32, 4.85) 0.002	1.41 (1.10, 1.80) 0.006	0.21 (0.07, 0.35) 0.002	
Age Group (Years)						0.634
< 65	32/ 60 (53.3) (40.0, 66.3)	94/132 (71.2) (62.7, 78.8)	2.39 (1.17, 4.74) 0.008	1.37 (1.06, 1.77) 0.018	0.19 (0.05, 0.34) 0.009	
>= 65	5/ 11 (45.5) (16.7, 76.6)	7/ 9 (77.8) (40.0, 97.2)	4.65 (0.41, 64.65) 0.150	1.96 (0.73, 5.27) 0.184	0.37 (-0.09, 0.82) 0.112	
Sex						0.844
Male	6/ 17 (35.3) (14.2, 61.7)	23/ 41 (56.1) (39.7, 71.5)	2.48 (0.65, 9.14) 0.144	1.62 (0.81, 3.26) 0.176	0.22 (-0.05, 0.49) 0.115	
Female	31/ 54 (57.4) (43.2, 70.8)	78/100 (78.0) (68.6, 85.7)	2.95 (1.30, 6.42) 0.004	1.39 (1.08, 1.79) 0.010	0.22 (0.07, 0.38) 0.005	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-emotions-resp-itt-a.sas Date: 15:58/14AUG2025

Table 35.2.8.4.4.1a
Proportion of Patients with MC-QoL Emotions Domain Score Change from Baseline <= -15 Points by C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients MC-QoL Emotions Domain Score Change from Baseline <= -15 Points	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Region						0.868
North America	15/ 33 (45.5) (28.1, 63.6)	40/ 60 (66.7) (53.3, 78.3)	2.82 (1.00, 7.72) 0.029	1.53 (1.01, 2.33) 0.046	0.24 (0.03, 0.44) 0.023	
Europe	22/ 38 (57.9) (40.8, 73.7)	61/ 81 (75.3) (64.5, 84.2)	2.27 (0.91, 5.48) 0.052	1.31 (0.97, 1.76) 0.079	0.18 (-0.01, 0.36) 0.057	
Country						0.930
BEL	1/ 1 (100.0) (2.5, 100.0)	3/ 3 (100.0) (29.2, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
CAN	2/ 5 (40.0) (5.3, 85.3)	5/ 8 (62.5) (24.5, 91.5)	2.67 (0.03, 196.19) 0.515	1.56 (0.26, 9.47) 0.632	0.20 (-0.42, 0.82) 0.525	
CHE	0/ 1 (0.0) (0.0, 97.5)	1/ 2 (50.0) (1.3, 98.7)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DEU	10/ 15 (66.7) (38.4, 88.2)	10/ 19 (52.6) (28.9, 75.6)	0.58 (0.12, 2.91) 0.479	0.81 (0.48, 1.38) >0.999	-0.13 (-0.46, 0.20) 0.453	
DNK	0/0	1/ 1 (100.0) (2.5, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-emotions-resp-itt-a.sas Date: 15:58/14AUG2025

Table 35.2.8.4.4.1a
Proportion of Patients with MC-QoL Emotions Domain Score Change from Baseline <= -15 Points by C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients MC-QoL Emotions Domain Score Change from Baseline <= -15 Points	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
ESP	2/ 3 (66.7) (9.4, 99.2)	11/ 14 (78.6) (49.2, 95.3)	NE (0.07, NE) 0.248	1.38 (0.63, 3.01) 0.416	0.24 (-0.20, 0.68) 0.282	
FRA	4/ 6 (66.7) (22.3, 95.7)	9/ 11 (81.8) (48.2, 97.7)	8.20 (0.17, 495.81) 0.230	1.44 (0.75, 2.75) 0.271	0.28 (-0.13, 0.70) 0.185	
GBR	3/ 5 (60.0) (14.7, 94.7)	10/ 11 (90.9) (58.7, 99.8)	3.73 (0.18, 288.03) 0.236	1.55 (0.59, 4.05) 0.374	0.30 (-0.23, 0.83) 0.266	
ITA	0/0	3/ 4 (75.0) (19.4, 99.4)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
NLD	0/ 3 (0.0) (0.0, 70.8)	8/ 9 (88.9) (51.8, 99.7)	NE (0.32, NE) 0.114	NE (NE, NE) NE	0.67 (0.13, 1.00) 0.014	
NOR	1/ 3 (33.3) (0.8, 90.6)	3/ 5 (60.0) (14.7, 94.7)	NE (0.04, NE) 0.414	1.60 (0.51, 5.00) 0.418	0.21 (-0.21, 0.64) 0.323	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-emotions-resp-itt-a.sas Date: 15:58/14AUG2025

Table 35.2.8.4.4.1a
Proportion of Patients with MC-QoL Emotions Domain Score Change from Baseline <= -15 Points by C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients MC-QoL Emotions Domain Score Change from Baseline <= -15 Points	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
SWE	1/ 1 (100.0) (2.5, 100.0)	2/ 2 (100.0) (15.8, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
USA	13/ 28 (46.4) (27.5, 66.1)	35/ 52 (67.3) (52.9, 79.7)	2.73 (0.91, 8.00) 0.047	1.51 (0.97, 2.36) 0.067	0.24 (0.01, 0.46) 0.039	
Baseline ISM Status						0.720
Moderate	11/ 26 (42.3) (23.4, 63.1)	35/ 52 (67.3) (52.9, 79.7)	2.99 (0.99, 8.89) 0.029	1.62 (0.99, 2.65) 0.053	0.26 (0.03, 0.49) 0.024	
Severe	26/ 45 (57.8) (42.2, 72.3)	65/ 87 (74.7) (64.3, 83.4)	2.32 (0.98, 5.39) 0.034	1.31 (1.00, 1.73) 0.054	0.18 (0.01, 0.35) 0.037	
Baseline Serum Tryptase (ng/mL)						0.873
< 20	9/ 15 (60.0) (32.3, 83.7)	21/ 28 (75.0) (55.1, 89.3)	3.17 (0.54, 21.33) 0.146	1.36 (0.86, 2.14) 0.190	0.21 (-0.06, 0.48) 0.136	
>= 20	28/ 56 (50.0) (36.3, 63.7)	80/113 (70.8) (61.5, 79.0)	2.46 (1.19, 5.00) 0.008	1.42 (1.07, 1.89) 0.017	0.21 (0.05, 0.37) 0.008	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-emotions-resp-itt-a.sas Date: 15:58/14AUG2025

Table 35.2.8.4.4.1a
Proportion of Patients with MC-QoL Emotions Domain Score Change from Baseline <= -15 Points by C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients MC-QoL Emotions Domain Score Change from Baseline <= %-15 Points	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.908
0 or 1	35/ 67 (52.2) (39.7, 64.6)	94/131 (71.8) (63.2, 79.3)	2.60 (1.30, 5.03) 0.003	1.41 (1.10, 1.81) 0.008	0.21 (0.07, 0.35) 0.003	
2+	2/ 4 (50.0) (6.8, 93.2)	7/ 10 (70.0) (34.8, 93.3)	2.60 (0.11, 163.69) 0.463	1.44 (0.51, 4.07) 0.486	0.22 (-0.35, 0.79) 0.447	
Prior TKI therapy						0.578
Yes	3/ 4 (75.0) (19.4, 99.4)	8/ 10 (80.0) (44.4, 97.5)	NE (0.09, NE) 0.197	1.47 (0.60, 3.60) 0.401	0.28 (-0.11, 0.68) 0.160	
No	34/ 67 (50.7) (38.2, 63.2)	93/131 (71.0) (62.4, 78.6)	2.63 (1.32, 5.08) 0.003	1.43 (1.11, 1.86) 0.006	0.22 (0.08, 0.36) 0.002	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-emotions-resp-itt-a.sas Date: 15:58/14AUG2025

Table 35.2.8.4.5.1a
Proportion of Patients with MC-QoL Skin Domain Score Change from Baseline <= -15 Points by C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients MC-QoL Skin Domain Score Change from Baseline <= -15 Points	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Overall	50/ 71 (70.4) (58.4, 80.7)	99/141 (70.2) (61.9, 77.6)	1.04 (0.52, 2.07) 0.902	1.01 (0.84, 1.22) 0.904	0.01 (-0.12, 0.14) 0.903	
Age Group (Years)						0.920
< 65	42/ 60 (70.0) (56.8, 81.2)	92/132 (69.7) (61.1, 77.4)	1.09 (0.51, 2.29) 0.799	1.03 (0.84, 1.25) 0.802	0.02 (-0.12, 0.15) 0.799	
>= 65	8/ 11 (72.7) (39.0, 94.0)	7/ 9 (77.8) (40.0, 97.2)	1.32 (0.09, 22.13) 0.803	1.08 (0.57, 2.04) 0.807	0.06 (-0.38, 0.49) 0.798	
Sex						0.783
Male	10/ 17 (58.8) (32.9, 81.6)	23/ 41 (56.1) (39.7, 71.5)	0.95 (0.24, 3.62) 0.941	0.98 (0.62, 1.56) >0.999	-0.01 (-0.28, 0.26) 0.939	
Female	40/ 54 (74.1) (60.3, 85.0)	76/100 (76.0) (66.4, 84.0)	1.12 (0.47, 2.60) 0.779	1.03 (0.85, 1.25) 0.784	0.02 (-0.12, 0.16) 0.780	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-skin-resp-itt-a.sas Date: 15:59/14AUG2025

Table 35.2.8.4.5.1a
Proportion of Patients with MC-QoL Skin Domain Score Change from Baseline <= -15 Points by C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients MC-QoL Skin Domain Score Change from Baseline <= -15 Points	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Region						0.312
North America	24/ 33 (72.7) (54.5, 86.7)	39/ 60 (65.0) (51.6, 76.9)	0.76 (0.25, 2.28) 0.598	0.93 (0.70, 1.23) >0.999	-0.05 (-0.24, 0.14) 0.587	
Europe	26/ 38 (68.4) (51.3, 82.5)	60/ 81 (74.1) (63.1, 83.2)	1.34 (0.51, 3.37) 0.505	1.09 (0.84, 1.40) 0.520	0.06 (-0.12, 0.23) 0.511	
Country						0.885
BEL	1/ 1 (100.0) (2.5, 100.0)	2/ 3 (66.7) (9.4, 99.2)	0.00 (0.00, 19.00) 0.317	0.00 (NE, NE) NE	-1.00 (-1.00, -1.00) NE	
CAN	3/ 5 (60.0) (14.7, 94.7)	5/ 8 (62.5) (24.5, 91.5)	0.00 (0.00, 8.47) 0.362	0.63 (0.29, 1.36) >0.999	-0.28 (-0.62, 0.06) 0.103	
CHE	0/ 1 (0.0) (0.0, 97.5)	2/ 2 (100.0) (15.8, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
DEU	10/ 15 (66.7) (38.4, 88.2)	14/ 19 (73.7) (48.8, 90.9)	1.61 (0.27, 9.03) 0.559	1.15 (0.72, 1.81) 0.561	0.09 (-0.21, 0.40) 0.546	
DNK	0/0	1/ 1 (100.0) (2.5, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-skin-resp-itt-a.sas Date: 15:59/14AUG2025

Table 35.2.8.4.5.1a
Proportion of Patients with MC-QoL Skin Domain Score Change from Baseline <= -15 Points by C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients MC-QoL Skin Domain Score Change from Baseline <= -15 Points	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
ESP	2/ 3 (66.7) (9.4, 99.2)	10/ 14 (71.4) (41.9, 91.6)	1.00 (0.01, 104.37) >0.999	1.00 (0.47, 2.11) >0.999	0.00 (-0.51, 0.51) >0.999	
FRA	5/ 6 (83.3) (35.9, 99.6)	10/ 11 (90.9) (58.7, 99.8)	5.00 (0.03, 469.25) 0.378	1.20 (0.72, 2.02) 0.480	0.16 (-0.20, 0.51) 0.389	
GBR	5/ 5 (100.0) (47.8, 100.0)	6/ 11 (54.5) (23.4, 83.3)	0.00 (0.00, 2.17) 0.116	0.57 (0.32, 1.03) >0.999	-0.43 (-0.77, -0.08) 0.016	
ITA	0/0	3/ 4 (75.0) (19.4, 99.4)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
NLD	1/ 3 (33.3) (0.8, 90.6)	8/ 9 (88.9) (51.8, 99.7)	4.00 (0.07, 352.00) 0.456	2.00 (0.33, 11.97) 0.448	0.33 (-0.42, 1.00) 0.386	
NOR	1/ 3 (33.3) (0.8, 90.6)	2/ 5 (40.0) (5.3, 85.3)	1.20 (0.01, 104.50) 0.922	1.10 (0.21, 5.79) 0.910	0.04 (-0.60, 0.67) 0.912	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-skin-resp-itt-a.sas Date: 15:59/14AUG2025

Table 35.2.8.4.5.1a
Proportion of Patients with MC-QoL Skin Domain Score Change from Baseline <= -15 Points by C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients MC-QoL Skin Domain Score Change from Baseline <= -15 Points	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
Country (Cont.)						
SWE	1/ 1 (100.0) (2.5, 100.0)	2/ 2 (100.0) (15.8, 100.0)	NE (NE, NE) NE	NE (NE, NE) NE	NE (NE, NE) NE	
USA	21/ 28 (75.0) (55.1, 89.3)	34/ 52 (65.4) (50.9, 78.0)	0.73 (0.21, 2.47) 0.582	0.92 (0.69, 1.23) >0.999	-0.06 (-0.26, 0.14) 0.570	
Baseline ISM Status						0.702
Moderate	14/ 26 (53.8) (33.4, 73.4)	30/ 52 (57.7) (43.2, 71.3)	1.20 (0.42, 3.43) 0.709	1.08 (0.70, 1.68) 0.715	0.05 (-0.19, 0.28) 0.707	
Severe	36/ 45 (80.0) (65.4, 90.4)	68/ 87 (78.2) (68.0, 86.3)	0.92 (0.33, 2.41) 0.857	0.98 (0.81, 1.19) >0.999	-0.01 (-0.16, 0.13) 0.857	
Baseline Serum Tryptase (ng/mL)						0.474
< 20	12/ 15 (80.0) (51.9, 95.7)	19/ 28 (67.9) (47.6, 84.1)	0.68 (0.09, 4.12) 0.624	0.91 (0.63, 1.32) >0.999	-0.07 (-0.33, 0.19) 0.617	
>= 20	38/ 56 (67.9) (54.0, 79.7)	80/113 (70.8) (61.5, 79.0)	1.14 (0.52, 2.44) 0.716	1.04 (0.84, 1.29) 0.720	0.03 (-0.12, 0.17) 0.718	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-skin-resp-itt-a.sas Date: 15:59/14AUG2025

Table 35.2.8.4.5.1a
Proportion of Patients with MC-QoL Skin Domain Score Change from Baseline <= -15 Points by C7D1
Intent-to-Treat Population, All Patients that reached C7D1 or EOS prior to C7D1, Part 2 (Part 2 Baseline)

Patients MC-QoL Skin Domain Score Change from Baseline <= -15 Points	Placebo (N=71) n/N (%) (95% CIs)	Avapritinib 25 mg (N=141) n/N (%) (95% CIs)	Odds Ratio (95% CIs) p-value [1]	Relative Risk (95% CIs) p-value [1]	Risk Difference (95% CIs) p-value [1]	Interaction [2]
ECOG Status						0.879
0 or 1	48/ 67 (71.6) (59.3, 82.0)	93/131 (71.0) (62.4, 78.6)	1.04 (0.50, 2.13) 0.910	1.01 (0.84, 1.22) 0.912	0.01 (-0.12, 0.14) 0.911	
2+	2/ 4 (50.0) (6.8, 93.2)	6/ 10 (60.0) (26.2, 87.8)	0.80 (0.01, 24.54) 0.894	0.93 (0.41, 2.11) >0.999	-0.04 (-0.52, 0.45) 0.880	
Prior TKI therapy						0.895
Yes	3/ 4 (75.0) (19.4, 99.4)	8/ 10 (80.0) (44.4, 97.5)	1.13 (0.01, 136.93) 0.896	1.06 (0.24, 4.74) 0.937	0.04 (-0.71, 0.79) 0.921	
No	47/ 67 (70.1) (57.7, 80.7)	91/131 (69.5) (60.8, 77.2)	1.04 (0.51, 2.12) 0.900	1.01 (0.83, 1.23) 0.901	0.01 (-0.12, 0.14) 0.899	

Abbreviations: MC-QoL = Mastocytosis Quality of Life Questionnaire, CI = Confidence Interval
Note: Patient reached C7D1 or EOS prior to C7D1 with missing baseline or C7D1 assessment will be counted in the denominator.
[1] Odds Ratio (OR), Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo. OR>1 or RR>1 or RD>0 suggest favoring Avapritinib 25 mg compared to placebo. Two-sided p-value for OR is from Cochran-Mantel-Haenszel test. Two-sided p-value for RR is based on asymptotic normal approximation of log transformed Mantel-Haenszel estimate of the common relative risk. Two-sided p-value for RD is based on the Mantel-Haenszel test. All three tests controlled for randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL) and Baseline ISM status (moderate vs. severe).
[2] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-mcqol-skin-resp-itt-a.sas Date: 15:59/14AUG2025

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	56	126	11	9	
Mean (StdDev)	37.13 (11.891)	37.35 (11.445)	42.74 (12.634)	38.75 (12.929)	
Median	35.48	39.69	48.10	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	39.40 (11.470)	40.41 (11.994)	45.04 (7.778)	44.36 (11.982)	
Median	39.69	39.69	48.10	48.10	
Min, Max	22.9, 56.5	22.9, 56.5	31.3, 56.5	22.9, 56.5	
C2D1 CFB					
n	54	123	11	9	
LS Mean (StdErr) [2]	1.65 (1.062)	2.36 (0.753)	0.00 (4.982)	0.00 (6.319)	
95% CI [2]	-0.45, 3.75	0.88, 3.85	-10.56, 10.56	-13.40, 13.40	
Difference (95% CI) in CFB [2]		0.71 (-1.56, 2.99)		0.00 (-9.85, 9.85)	
p-value [3]		0.536		>0.999	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	119	10	9	
Mean (StdDev)	39.09 (10.650)	40.89 (12.014)	43.05 (9.045)	43.42 (13.377)	
Median	39.69	39.69	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	31.3, 56.5	22.9, 56.5	
C3D1 CFB					
n	53	116	10	9	
LS Mean (StdErr) [2]	2.21 (1.137)	3.58 (0.799)	-1.29 (5.034)	0.82 (6.339)	
95% CI [2]	-0.03, 4.46	2.00, 5.16	-12.02, 9.45	-12.69, 14.33	
Difference (95% CI) in CFB [2]		1.37 (-1.08, 3.81)		2.10 (-7.95, 12.16)	
p-value [3]		0.271		0.662	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	39.53 (10.756)	41.37 (11.575)	42.09 (12.588)	42.49 (13.304)	
Median	39.69	39.69	39.69	48.10	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C4D1 CFB					
n	49	116	7	9	
LS Mean (StdErr) [2]	3.86 (1.301)	4.57 (0.907)	-2.56 (5.022)	2.67 (6.696)	
95% CI [2]	1.28, 6.43	2.77, 6.36	-13.50, 8.39	-11.92, 17.26	
Difference (95% CI) in CFB [2]		0.71 (-2.03, 3.45)		5.22 (-6.98, 17.43)	
p-value [3]		0.609		0.369	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	117	9	8	
Mean (StdDev)	40.14 (12.376)	41.77 (11.791)	41.56 (10.953)	40.74 (12.265)	
Median	39.69	39.69	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C5D1 CFB					
n	52	111	9	8	
LS Mean (StdErr) [2]	2.52 (1.290)	4.66 (0.924)	-1.60 (4.684)	-3.23 (6.071)	
95% CI [2]	-0.03, 5.07	2.83, 6.48	-11.72, 8.52	-16.35, 9.88	
Difference (95% CI) in CFB [2]		2.14 (-0.62, 4.89)		-1.64 (-11.86, 8.59)	
p-value [3]		0.128		0.735	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	38.75 (11.634)	42.56 (12.317)	42.84 (8.924)	42.49 (11.131)	
Median	39.69	39.69	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	31.3, 56.5	22.9, 56.5	
C6D1 CFB					
n	51	114	8	9	
LS Mean (StdErr) [2]	1.37 (1.294)	4.96 (0.905)	-1.54 (3.554)	-3.51 (4.783)	
95% CI [2]	-1.19, 3.92	3.17, 6.74	-9.22, 6.14	-13.84, 6.83	
Difference (95% CI) in CFB [2]		3.59 (0.82, 6.36)		-1.96 (-10.43, 6.51)	
p-value [3]		0.011		0.625	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	39.69 (11.053)	42.23 (12.468)	41.37 (13.035)	40.74 (10.487)	
Median	39.69	39.69	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C7D1 CFB					
n	49	113	10	8	
LS Mean (StdErr) [2]	1.45 (1.425)	3.97 (0.989)	-3.61 (5.993)	-4.21 (7.928)	
95% CI [2]	-1.37, 4.26	2.02, 5.93	-16.46, 9.25	-21.21, 12.80	
Difference (95% CI) in CFB [2]		2.53 (-0.48, 5.54)		-0.60 (-13.45, 12.25)	
Hedges'G (95% CI) in CFB		0.24 (-0.09, 0.59)		-0.03 (-1.04, 0.97)	
p-value [3]		0.099		0.922	
					0.650

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	56	126	11	9	
Mean (StdDev)	33.63 (7.335)	34.59 (8.649)	39.41 (8.388)	37.51 (8.979)	
Median	30.03	34.51	39.00	39.00	
Min, Max	21.0, 48.0	21.0, 57.0	30.0, 52.5	25.5, 57.0	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	35.29 (9.179)	37.50 (10.145)	42.27 (8.300)	39.50 (9.898)	
Median	34.51	39.00	39.00	39.00	
Min, Max	21.0, 57.0	21.0, 57.0	30.0, 57.0	30.0, 57.0	
C2D1 CFB					
n	54	123	11	9	
LS Mean (StdErr) [2]	0.55 (1.086)	1.84 (0.770)	2.35 (2.435)	3.12 (3.088)	
95% CI [2]	-1.59, 2.69	0.32, 3.36	-2.81, 7.52	-3.43, 9.67	
Difference (95% CI) in CFB [2]		1.29 (-1.04, 3.62)		0.77 (-4.05, 5.58)	
p-value [3]		0.275		0.740	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	119	10	9	
Mean (StdDev)	36.01 (9.345)	39.04 (10.431)	41.25 (10.843)	41.50 (7.482)	
Median	34.51	39.00	41.25	39.00	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 57.0	34.5, 52.5	
C3D1 CFB					
n	53	116	10	9	
LS Mean (StdErr) [2]	1.73 (1.181)	4.08 (0.831)	1.06 (3.399)	5.18 (4.279)	
95% CI [2]	-0.61, 4.06	2.44, 5.72	-6.18, 8.30	-3.95, 14.30	
Difference (95% CI) in CFB [2]		2.35 (-0.19, 4.89)		4.12 (-2.67, 10.90)	
p-value [3]		0.069		0.216	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	118	7	9	
Mean (StdDev)	36.46 (10.058)	39.57 (10.360)	40.29 (9.942)	44.49 (8.024)	
Median	34.51	39.00	39.00	43.49	
Min, Max	21.0, 57.0	21.0, 57.0	25.5, 52.5	30.0, 52.5	
C4D1 CFB					
n	49	114	7	9	
LS Mean (StdErr) [2]	2.73 (1.248)	4.61 (0.878)	0.04 (4.228)	7.29 (5.637)	
95% CI [2]	0.27, 5.19	2.88, 6.35	-9.17, 9.26	-4.99, 19.57	
Difference (95% CI) in CFB [2]		1.88 (-0.74, 4.51)		7.25 (-3.03, 17.52)	
p-value [3]		0.159		0.150	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	117	9	8	
Mean (StdDev)	37.29 (9.163)	39.16 (10.055)	36.51 (11.248)	46.30 (7.174)	
Median	39.00	39.00	39.00	45.74	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 57.0	39.0, 57.0	
C5D1 CFB					
n	52	111	9	8	
LS Mean (StdErr) [2]	3.38 (1.131)	4.57 (0.810)	-2.10 (5.476)	9.00 (7.098)	
95% CI [2]	1.15, 5.62	2.97, 6.17	-13.93, 9.73	-6.33, 24.33	
Difference (95% CI) in CFB [2]		1.19 (-1.23, 3.61)		11.10 (-0.85, 23.05)	
p-value [3]		0.333		0.066	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	35.76 (9.844)	40.61 (10.343)	38.44 (10.580)	43.49 (8.694)	
Median	34.51	39.00	36.76	47.98	
Min, Max	21.0, 57.0	21.0, 57.0	25.5, 57.0	30.0, 52.5	
C6D1 CFB					
n	51	114	8	9	
LS Mean (StdErr) [2]	1.52 (1.297)	5.35 (0.908)	1.01 (4.309)	6.92 (5.799)	
95% CI [2]	-1.04, 4.08	3.56, 7.15	-8.30, 10.32	-5.61, 19.45	
Difference (95% CI) in CFB [2]		3.83 (1.06, 6.61)		5.91 (-4.36, 16.18)	
p-value [3]		0.007		0.236	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	37.36 (10.369)	40.51 (10.907)	41.25 (10.634)	40.69 (7.936)	
Median	39.00	39.00	39.00	39.00	
Min, Max	21.0, 57.0	21.0, 57.0	30.0, 57.0	25.5, 52.5	
C7D1 CFB					
n	49	113	10	8	
LS Mean (StdErr) [2]	2.88 (1.406)	4.88 (0.976)	0.11 (4.448)	1.50 (5.884)	
95% CI [2]	0.11, 5.66	2.95, 6.80	-9.43, 9.65	-11.12, 14.12	
Difference (95% CI) in CFB [2]		1.99 (-0.98, 4.96)		1.39 (-8.15, 10.93)	
Hedges'G (95% CI) in CFB		0.19 (-0.14, 0.54)		0.09 (-0.91, 1.11)	
p-value [3]		0.187		0.759	
					>0.999

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	56	125	11	9	
Mean (StdDev)	30.95 (10.726)	32.16 (11.811)	40.00 (8.309)	32.84 (8.894)	
Median	26.00	26.00	36.27	26.00	
Min, Max	15.7, 56.8	15.7, 56.8	26.0, 56.8	26.0, 46.5	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	34.67 (11.349)	38.52 (12.690)	41.87 (9.595)	38.55 (11.225)	
Median	36.27	36.27	36.27	36.27	
Min, Max	15.7, 56.8	15.7, 56.8	26.0, 56.8	26.0, 56.8	
C2D1 CFB					
n	54	122	11	9	
LS Mean (StdErr) [2]	1.78 (1.527)	4.88 (1.093)	1.38 (3.751)	5.89 (4.758)	
95% CI [2]	-1.23, 4.80	2.73, 7.04	-6.57, 9.33	-4.20, 15.97	
Difference (95% CI) in CFB [2]		3.10 (-0.18, 6.37)		4.51 (-2.91, 11.92)	
p-value [3]		0.064		0.216	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	119	10	9	
Mean (StdDev)	35.91 (11.477)	39.38 (12.149)	41.40 (8.728)	43.12 (10.270)	
Median	36.27	46.54	41.40	46.54	
Min, Max	15.7, 56.8	15.7, 56.8	26.0, 56.8	26.0, 56.8	
C3D1 CFB					
n	53	115	10	9	
LS Mean (StdErr) [2]	4.60 (1.440)	7.46 (1.022)	0.29 (4.192)	8.84 (5.279)	
95% CI [2]	1.75, 7.44	5.45, 9.48	-8.65, 9.22	-2.41, 20.09	
Difference (95% CI) in CFB [2]		2.87 (-0.23, 5.97)		8.56 (0.19, 16.93)	
p-value [3]		0.070		0.046	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	119	7	9	
Mean (StdDev)	35.88 (10.651)	39.03 (12.804)	39.20 (11.428)	40.83 (11.610)	
Median	36.27	36.27	36.27	36.27	
Min, Max	15.7, 56.8	15.7, 56.8	26.0, 56.8	26.0, 56.8	
C4D1 CFB					
n	49	114	7	9	
LS Mean (StdErr) [2]	3.73 (1.647)	6.07 (1.174)	-1.61 (4.208)	10.40 (5.611)	
95% CI [2]	0.48, 6.99	3.75, 8.39	-10.78, 7.56	-1.82, 22.63	
Difference (95% CI) in CFB [2]		2.33 (-1.12, 5.79)		12.02 (1.79, 22.24)	
p-value [3]		0.184		0.025	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	117	9	8	
Mean (StdDev)	35.89 (12.017)	38.73 (12.981)	37.41 (13.036)	46.54 (12.276)	
Median	36.27	36.27	36.27	51.67	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	26.0, 56.8	
C5D1 CFB					
n	52	110	9	8	
LS Mean (StdErr) [2]	3.74 (1.581)	6.14 (1.143)	-2.88 (5.601)	10.96 (7.260)	
95% CI [2]	0.62, 6.86	3.88, 8.39	-14.98, 9.22	-4.72, 26.64	
Difference (95% CI) in CFB [2]		2.40 (-0.98, 5.78)		13.84 (1.61, 26.06)	
p-value [3]		0.163		0.029	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	53	120	8	9	
Mean (StdDev)	35.11 (12.685)	39.95 (12.826)	37.55 (13.929)	45.40 (13.036)	
Median	36.27	46.54	41.40	46.54	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	26.0, 56.8	
C6D1 CFB					
n	50	113	8	9	
LS Mean (StdErr) [2]	2.84 (1.607)	6.99 (1.129)	-2.23 (5.127)	14.55 (6.900)	
95% CI [2]	-0.33, 6.01	4.76, 9.22	-13.30, 8.85	-0.36, 29.46	
Difference (95% CI) in CFB [2]		4.15 (0.71, 7.60)		16.78 (4.55, 29.00)	
p-value [3]		0.018		0.011	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	37.06 (11.477)	39.46 (13.619)	41.40 (11.093)	42.69 (10.893)	
Median	36.27	36.27	41.40	41.40	
Min, Max	15.7, 56.8	15.7, 56.8	26.0, 56.8	26.0, 56.8	
C7D1 CFB					
n	49	112	10	8	
LS Mean (StdErr) [2]	3.24 (1.674)	4.80 (1.174)	-0.24 (4.175)	6.85 (5.522)	
95% CI [2]	-0.07, 6.55	2.48, 7.11	-9.20, 8.71	-5.00, 18.69	
Difference (95% CI) in CFB [2]		1.56 (-1.98, 5.10)		7.09 (-1.86, 16.04)	
Hedges'G (95% CI) in CFB		0.13 (-0.21, 0.47)		0.47 (-0.48, 1.56)	
p-value [3]		0.386		0.111	
					0.265

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	56	126	11	9	
Mean (StdDev)	32.78 (10.374)	33.86 (9.831)	39.12 (9.216)	33.35 (6.558)	
Median	30.05	30.05	44.92	30.05	
Min, Max	19.4, 61.9	19.4, 55.5	30.0, 55.5	30.0, 44.9	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	34.95 (10.784)	35.89 (10.625)	42.79 (9.163)	34.53 (12.409)	
Median	30.05	30.05	44.92	30.05	
Min, Max	19.4, 55.5	19.4, 55.5	30.0, 55.5	19.4, 55.5	
C2D1 CFB					
n	54	123	11	9	
LS Mean (StdErr) [2]	1.44 (1.252)	1.95 (0.888)	1.79 (4.492)	-1.63 (5.697)	
95% CI [2]	-1.03, 3.91	0.20, 3.70	-7.73, 11.31	-13.71, 10.45	
Difference (95% CI) in CFB [2]		0.51 (-2.17, 3.19)		-3.42 (-12.30, 5.46)	
p-value [3]		0.707		0.426	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	119	10	9	
Mean (StdDev)	34.41 (9.748)	37.26 (11.161)	39.61 (10.798)	39.49 (9.567)	
Median	30.05	30.05	37.48	44.92	
Min, Max	19.4, 55.5	19.4, 61.9	30.0, 55.5	30.0, 55.5	
C3D1 CFB					
n	53	116	10	9	
LS Mean (StdErr) [2]	0.86 (1.388)	3.36 (0.976)	-1.06 (3.569)	3.90 (4.494)	
95% CI [2]	-1.88, 3.60	1.43, 5.28	-8.67, 6.54	-5.68, 13.47	
Difference (95% CI) in CFB [2]		2.50 (-0.48, 5.48)		4.96 (-2.17, 12.09)	
p-value [3]		0.100		0.159	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	35.46 (10.709)	37.38 (11.137)	40.06 (10.094)	39.49 (9.567)	
Median	30.05	44.92	44.92	44.92	
Min, Max	19.4, 61.9	19.4, 55.5	30.0, 55.5	30.0, 55.5	
C4D1 CFB					
n	49	116	7	9	
LS Mean (StdErr) [2]	1.48 (1.517)	2.79 (1.058)	-0.23 (3.193)	4.53 (4.257)	
95% CI [2]	-1.51, 4.48	0.70, 4.88	-7.19, 6.73	-4.74, 13.81	
Difference (95% CI) in CFB [2]		1.31 (-1.88, 4.50)		4.76 (-3.00, 12.52)	
p-value [3]		0.420		0.206	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	117	9	8	
Mean (StdDev)	36.26 (10.487)	37.96 (10.889)	36.66 (7.838)	38.81 (9.993)	
Median	30.05	44.92	30.05	37.48	
Min, Max	19.4, 61.9	19.4, 55.5	30.0, 44.9	30.0, 55.5	
C5D1 CFB					
n	52	111	9	8	
LS Mean (StdErr) [2]	3.09 (1.477)	3.90 (1.058)	-2.00 (3.538)	5.03 (4.586)	
95% CI [2]	0.18, 6.01	1.81, 5.99	-9.64, 5.65	-4.88, 14.93	
Difference (95% CI) in CFB [2]		0.81 (-2.35, 3.96)		7.02 (-0.70, 14.74)	
p-value [3]		0.615		0.071	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	35.87 (11.417)	38.77 (11.265)	38.81 (9.993)	38.31 (7.838)	
Median	30.05	44.92	37.48	44.92	
Min, Max	19.4, 61.9	19.4, 55.5	30.0, 55.5	30.0, 44.9	
C6D1 CFB					
n	51	114	8	9	
LS Mean (StdErr) [2]	2.25 (1.469)	4.59 (1.028)	-1.49 (3.426)	2.48 (4.612)	
95% CI [2]	-0.66, 5.15	2.55, 6.62	-8.89, 5.91	-7.48, 12.44	
Difference (95% CI) in CFB [2]		2.34 (-0.81, 5.48)		3.97 (-4.20, 12.13)	
p-value [3]		0.144		0.313	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	35.81 (10.828)	39.12 (11.146)	41.09 (10.350)	37.48 (7.949)	
Median	30.05	44.92	44.92	37.48	
Min, Max	19.4, 55.5	19.4, 55.5	30.0, 55.5	30.0, 44.9	
C7D1 CFB					
n	49	113	10	8	
LS Mean (StdErr) [2]	1.32 (1.552)	4.21 (1.077)	-0.99 (3.626)	-0.53 (4.797)	
95% CI [2]	-1.75, 4.38	2.08, 6.34	-8.76, 6.79	-10.82, 9.76	
Difference (95% CI) in CFB [2]		2.89 (-0.38, 6.17)		0.46 (-7.32, 8.23)	
Hedges'G (95% CI) in CFB		0.26 (-0.08, 0.60)		0.03 (-0.97, 1.05)	
p-value [3]		0.083		0.902	
					0.861

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	56	126	11	9	
Mean (StdDev)	38.60 (8.717)	37.48 (8.053)	43.57 (9.112)	39.33 (12.381)	
Median	38.25	38.25	48.00	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 57.8	28.5, 57.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	39.76 (8.724)	39.93 (9.411)	46.23 (8.524)	40.42 (11.723)	
Median	38.25	38.25	48.00	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	38.2, 67.5	28.5, 57.8	
C2D1 CFB					
n	54	123	11	9	
LS Mean (StdErr) [2]	1.06 (1.203)	2.82 (0.853)	-2.97 (3.486)	-5.91 (4.421)	
95% CI [2]	-1.31, 3.43	1.13, 4.50	-10.36, 4.42	-15.28, 3.46	
Difference (95% CI) in CFB [2]		1.76 (-0.82, 4.33)		-2.93 (-9.82, 3.96)	
p-value [3]		0.180		0.380	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	119	10	9	
Mean (StdDev)	40.82 (9.129)	40.54 (9.478)	46.05 (11.073)	44.75 (13.794)	
Median	38.25	38.25	48.00	48.00	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 67.5	28.5, 57.8	
C3D1 CFB					
n	53	116	10	9	
LS Mean (StdErr) [2]	2.38 (1.205)	3.21 (0.848)	5.15 (4.412)	6.77 (5.555)	
95% CI [2]	-0.00, 4.76	1.53, 4.88	-4.26, 14.55	-5.07, 18.61	
Difference (95% CI) in CFB [2]		0.83 (-1.76, 3.42)		1.63 (-7.19, 10.44)	
p-value [3]		0.529		0.700	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	39.72 (8.205)	40.53 (10.015)	43.82 (11.060)	49.09 (10.281)	
Median	38.25	38.25	48.00	48.00	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 57.8	28.5, 57.8	
C4D1 CFB					
n	49	116	7	9	
LS Mean (StdErr) [2]	1.36 (1.452)	2.60 (1.012)	0.29 (4.743)	5.26 (6.324)	
95% CI [2]	-1.51, 4.23	0.61, 4.60	-10.05, 10.62	-8.52, 19.04	
Difference (95% CI) in CFB [2]		1.24 (-1.81, 4.30)		4.97 (-6.56, 16.50)	
p-value [3]		0.422		0.366	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	117	9	8	
Mean (StdDev)	40.55 (9.379)	41.33 (9.892)	41.50 (9.754)	44.35 (11.585)	
Median	38.25	38.25	38.25	48.00	
Min, Max	28.5, 57.8	28.5, 67.5	28.5, 57.8	28.5, 57.8	
C5D1 CFB					
n	52	111	9	8	
LS Mean (StdErr) [2]	2.31 (1.380)	3.93 (0.989)	2.57 (6.277)	6.64 (8.136)	
95% CI [2]	-0.41, 5.04	1.97, 5.88	-10.99, 16.13	-10.94, 24.22	
Difference (95% CI) in CFB [2]		1.61 (-1.34, 4.56)		4.06 (-9.63, 17.76)	
p-value [3]		0.282		0.533	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	39.33 (9.218)	42.39 (9.849)	39.47 (8.140)	45.84 (11.723)	
Median	38.25	38.25	38.25	48.00	
Min, Max	28.5, 57.8	28.5, 67.5	28.5, 48.0	28.5, 57.8	
C6D1 CFB					
n	51	114	8	9	
LS Mean (StdErr) [2]	1.22 (1.319)	4.79 (0.923)	-2.44 (4.352)	-0.81 (5.857)	
95% CI [2]	-1.39, 3.82	2.96, 6.61	-11.84, 6.96	-13.47, 11.84	
Difference (95% CI) in CFB [2]		3.57 (0.75, 6.39)		1.63 (-8.75, 12.00)	
p-value [3]		0.014		0.740	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	40.69 (10.013)	41.94 (10.237)	46.05 (11.990)	44.35 (12.704)	
Median	38.25	38.25	48.00	43.13	
Min, Max	28.5, 57.8	28.5, 67.5	28.5, 67.5	28.5, 57.8	
C7D1 CFB					
n	49	113	10	8	
LS Mean (StdErr) [2]	2.70 (1.383)	4.01 (0.960)	4.18 (5.371)	4.88 (7.105)	
95% CI [2]	-0.03, 5.44	2.12, 5.91	-7.34, 15.70	-10.36, 20.12	
Difference (95% CI) in CFB [2]		1.31 (-1.61, 4.23)		0.70 (-10.82, 12.22)	
Hedges'G (95% CI) in CFB		0.13 (-0.21, 0.47)		0.04 (-0.96, 1.05)	
p-value [3]		0.377		0.899	
					0.511

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	56	126	11	9	
Mean (StdDev)	35.93 (12.100)	37.31 (11.274)	42.59 (8.021)	42.90 (8.586)	
Median	36.29	36.29	36.29	36.29	
Min, Max	16.5, 56.1	16.5, 56.1	36.3, 56.1	36.3, 56.1	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	39.53 (10.890)	40.86 (11.598)	41.69 (11.185)	41.79 (7.202)	
Median	36.29	46.20	36.29	36.29	
Min, Max	16.5, 56.1	16.5, 56.1	26.4, 56.1	36.3, 56.1	
C2D1 CFB					
n	54	123	11	9	
LS Mean (StdErr) [2]	2.52 (1.538)	2.98 (1.090)	-0.48 (3.663)	-0.56 (4.646)	
95% CI [2]	-0.51, 5.56	0.83, 5.14	-8.25, 7.28	-10.41, 9.29	
Difference (95% CI) in CFB [2]		0.46 (-2.83, 3.76)		-0.08 (-7.32, 7.16)	
p-value [3]		0.782		0.981	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	119	10	9	
Mean (StdDev)	40.46 (11.542)	40.53 (11.870)	43.23 (9.405)	45.10 (9.200)	
Median	36.29	36.29	46.20	46.20	
Min, Max	16.5, 56.1	16.5, 56.1	26.4, 56.1	36.3, 56.1	
C3D1 CFB					
n	53	116	10	9	
LS Mean (StdErr) [2]	4.29 (1.452)	3.19 (1.021)	0.83 (4.797)	2.48 (6.040)	
95% CI [2]	1.42, 7.15	1.17, 5.20	-9.40, 11.05	-10.39, 15.35	
Difference (95% CI) in CFB [2]		-1.10 (-4.22, 2.02)		1.65 (-7.93, 11.23)	
p-value [3]		0.487		0.718	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	39.84 (11.015)	40.91 (12.323)	37.70 (12.045)	48.40 (8.262)	
Median	36.29	46.20	36.29	46.20	
Min, Max	16.5, 56.1	16.5, 56.1	16.5, 56.1	36.3, 56.1	
C4D1 CFB					
n	49	116	7	9	
LS Mean (StdErr) [2]	2.86 (1.673)	3.47 (1.166)	-1.65 (4.798)	7.16 (6.397)	
95% CI [2]	-0.45, 6.16	1.17, 5.77	-12.11, 8.80	-6.78, 21.10	
Difference (95% CI) in CFB [2]		0.61 (-2.91, 4.13)		8.81 (-2.85, 20.47)	
p-value [3]		0.731		0.126	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	117	9	8	
Mean (StdDev)	40.25 (12.157)	42.73 (12.024)	36.29 (9.914)	48.68 (8.788)	
Median	36.29	46.20	36.29	51.16	
Min, Max	16.5, 56.1	16.5, 56.1	26.4, 56.1	36.3, 56.1	
C5D1 CFB					
n	52	111	9	8	
LS Mean (StdErr) [2]	3.29 (1.691)	5.55 (1.212)	-3.76 (4.734)	2.29 (6.137)	
95% CI [2]	-0.05, 6.63	3.16, 7.94	-13.99, 6.46	-10.96, 15.55	
Difference (95% CI) in CFB [2]		2.26 (-1.35, 5.88)		6.06 (-4.27, 16.39)	
p-value [3]		0.218		0.227	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	39.22 (11.656)	42.07 (12.097)	38.76 (11.550)	50.61 (7.202)	
Median	36.29	46.20	36.29	56.11	
Min, Max	16.5, 56.1	16.5, 56.1	26.4, 56.1	36.3, 56.1	
C6D1 CFB					
n	51	114	8	9	
LS Mean (StdErr) [2]	2.25 (1.743)	4.36 (1.220)	-1.82 (4.678)	5.78 (6.296)	
95% CI [2]	-1.20, 5.69	1.95, 6.76	-11.92, 8.29	-7.82, 19.39	
Difference (95% CI) in CFB [2]		2.11 (-1.62, 5.84)		7.60 (-3.55, 18.75)	
p-value [3]		0.266		0.165	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	40.10 (11.967)	42.62 (12.496)	43.23 (11.495)	44.96 (8.274)	
Median	36.29	46.20	46.20	46.20	
Min, Max	16.5, 56.1	16.5, 56.1	26.4, 56.1	36.3, 56.1	
C7D1 CFB					
n	49	113	10	8	
LS Mean (StdErr) [2]	2.02 (1.816)	4.37 (1.261)	5.08 (4.447)	9.09 (5.882)	
95% CI [2]	-1.56, 5.61	1.88, 6.86	-4.46, 14.61	-3.53, 21.70	
Difference (95% CI) in CFB [2]		2.34 (-1.49, 6.18)		4.01 (-5.52, 13.55)	
Hedges'G (95% CI) in CFB		0.18 (-0.16, 0.52)		0.25 (-0.72, 1.30)	
p-value [3]		0.229		0.382	
					0.959

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	56	126	11	9	
Mean (StdDev)	36.91 (12.085)	38.00 (11.973)	40.27 (11.261)	41.11 (8.726)	
Median	33.75	39.27	39.27	39.27	
Min, Max	11.7, 55.8	11.7, 55.8	22.7, 55.8	33.8, 55.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	40.03 (11.346)	41.38 (11.837)	40.78 (11.601)	44.79 (8.726)	
Median	39.27	44.79	39.27	39.27	
Min, Max	17.2, 55.8	11.7, 55.8	22.7, 55.8	33.8, 55.8	
C2D1 CFB					
n	54	123	11	9	
LS Mean (StdErr) [2]	3.55 (1.410)	3.94 (1.000)	-2.09 (3.543)	0.79 (4.494)	
95% CI [2]	0.77, 6.33	1.97, 5.92	-9.60, 5.42	-8.74, 10.31	
Difference (95% CI) in CFB [2]		0.39 (-2.63, 3.41)		2.87 (-4.13, 9.88)	
p-value [3]		0.799		0.398	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	119	10	9	
Mean (StdDev)	41.11 (12.574)	41.45 (11.920)	40.93 (11.936)	47.86 (9.603)	
Median	44.79	44.79	44.79	50.31	
Min, Max	11.7, 55.8	11.7, 55.8	22.7, 55.8	33.8, 55.8	
C3D1 CFB					
n	53	116	10	9	
LS Mean (StdErr) [2]	4.67 (1.467)	4.53 (1.032)	-5.14 (4.359)	-0.08 (5.488)	
95% CI [2]	1.77, 7.56	2.49, 6.57	-14.43, 4.15	-11.77, 11.62	
Difference (95% CI) in CFB [2]		-0.14 (-3.29, 3.02)		5.06 (-3.65, 13.76)	
p-value [3]		0.932		0.235	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	119	7	9	
Mean (StdDev)	39.69 (12.094)	42.24 (11.954)	38.48 (12.103)	48.47 (9.152)	
Median	39.27	44.79	33.75	55.83	
Min, Max	17.2, 55.8	11.7, 55.8	22.7, 55.8	33.8, 55.8	
C4D1 CFB					
n	49	115	7	9	
LS Mean (StdErr) [2]	3.96 (1.691)	4.92 (1.179)	-3.73 (3.987)	1.46 (5.316)	
95% CI [2]	0.63, 7.30	2.59, 7.25	-12.42, 4.95	-10.12, 13.04	
Difference (95% CI) in CFB [2]		0.96 (-2.60, 4.52)		5.19 (-4.50, 14.89)	
p-value [3]		0.596		0.266	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	117	9	8	
Mean (StdDev)	42.38 (11.768)	42.67 (11.129)	33.14 (11.851)	50.31 (8.344)	
Median	44.79	44.79	33.75	55.83	
Min, Max	11.7, 55.8	11.7, 55.8	17.2, 55.8	33.8, 55.8	
C5D1 CFB					
n	52	111	9	8	
LS Mean (StdErr) [2]	5.11 (1.615)	4.76 (1.157)	-5.15 (5.944)	7.35 (7.704)	
95% CI [2]	1.92, 8.30	2.48, 7.05	-17.99, 7.69	-9.30, 23.99	
Difference (95% CI) in CFB [2]		-0.35 (-3.80, 3.10)		12.49 (-0.48, 25.46)	
p-value [3]		0.842		0.058	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	54	120	8	9	
Mean (StdDev)	41.42 (13.408)	41.94 (11.865)	39.27 (8.344)	49.70 (7.005)	
Median	44.79	44.79	33.75	50.31	
Min, Max	11.7, 55.8	11.7, 55.8	33.8, 55.8	39.3, 55.8	
C6D1 CFB					
n	51	114	8	9	
LS Mean (StdErr) [2]	4.02 (1.804)	3.85 (1.263)	-1.20 (3.959)	2.30 (5.328)	
95% CI [2]	0.46, 7.59	1.35, 6.34	-9.75, 7.36	-9.21, 13.81	
Difference (95% CI) in CFB [2]		-0.18 (-4.04, 3.68)		3.50 (-5.94, 12.93)	
p-value [3]		0.927		0.438	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	40.33 (12.606)	42.47 (11.773)	40.93 (14.022)	45.48 (8.569)	
Median	42.03	44.79	39.27	44.79	
Min, Max	11.7, 55.8	11.7, 55.8	11.7, 55.8	33.8, 55.8	
C7D1 CFB					
n	49	113	10	8	
LS Mean (StdErr) [2]	1.47 (1.627)	3.70 (1.129)	-1.38 (4.390)	1.38 (5.807)	
95% CI [2]	-1.74, 4.68	1.47, 5.93	-10.79, 8.04	-11.08, 13.83	
Difference (95% CI) in CFB [2]		2.23 (-1.21, 5.67)		2.76 (-6.66, 12.17)	
Hedges'G (95% CI) in CFB		0.19 (-0.15, 0.53)		0.17 (-0.81, 1.21)	
p-value [3]		0.202		0.540	
					0.587

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	56	126	11	9	
Mean (StdDev)	41.66 (9.515)	39.74 (10.134)	40.15 (11.035)	40.95 (11.290)	
Median	39.59	39.59	39.59	39.59	
Min, Max	27.4, 63.9	15.3, 63.9	21.3, 57.8	27.4, 63.9	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	42.32 (10.516)	41.64 (10.475)	41.81 (10.632)	42.97 (10.585)	
Median	39.59	39.59	39.59	39.59	
Min, Max	21.3, 63.9	15.3, 57.8	27.4, 57.8	33.5, 63.9	
C2D1 CFB					
n	54	123	11	9	
LS Mean (StdErr) [2]	0.79 (1.100)	2.44 (0.780)	3.78 (2.484)	4.92 (3.151)	
95% CI [2]	-1.38, 2.96	0.90, 3.98	-1.48, 9.05	-1.76, 11.60	
Difference (95% CI) in CFB [2]		1.65 (-0.71, 4.00)		1.14 (-3.77, 6.05)	
p-value [3]		0.169		0.630	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	119	10	9	
Mean (StdDev)	43.12 (10.343)	43.17 (11.099)	42.03 (10.806)	49.06 (8.662)	
Median	45.68	45.68	39.59	45.68	
Min, Max	15.3, 63.9	15.3, 63.9	27.4, 57.8	39.6, 63.9	
C3D1 CFB					
n	53	116	10	9	
LS Mean (StdErr) [2]	1.47 (1.269)	3.95 (0.892)	0.76 (4.253)	6.34 (5.355)	
95% CI [2]	-1.03, 3.98	2.19, 5.71	-8.30, 9.83	-5.08, 17.75	
Difference (95% CI) in CFB [2]		2.48 (-0.25, 5.21)		5.58 (-2.92, 14.07)	
p-value [3]		0.075		0.182	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	120	7	9	
Mean (StdDev)	43.38 (9.782)	44.06 (10.891)	37.86 (9.755)	47.71 (10.536)	
Median	39.59	45.68	39.59	45.68	
Min, Max	27.4, 63.9	15.3, 63.9	21.3, 51.8	33.5, 63.9	
C4D1 CFB					
n	49	116	7	9	
LS Mean (StdErr) [2]	2.97 (1.362)	5.23 (0.949)	1.55 (5.191)	7.47 (6.922)	
95% CI [2]	0.28, 5.66	3.35, 7.10	-9.76, 12.86	-7.61, 22.56	
Difference (95% CI) in CFB [2]		2.25 (-0.61, 5.12)		5.92 (-6.69, 18.54)	
p-value [3]		0.122		0.326	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	117	9	8	
Mean (StdDev)	43.91 (11.024)	43.44 (10.279)	37.57 (9.125)	50.24 (10.153)	
Median	45.68	45.68	39.59	51.76	
Min, Max	21.3, 63.9	15.3, 63.9	27.4, 57.8	39.6, 63.9	
C5D1 CFB					
n	52	111	9	8	
LS Mean (StdErr) [2]	2.31 (1.340)	3.95 (0.960)	0.37 (5.568)	8.31 (7.217)	
95% CI [2]	-0.34, 4.95	2.06, 5.85	-11.66, 12.39	-7.28, 23.90	
Difference (95% CI) in CFB [2]		1.65 (-1.22, 4.51)		7.94 (-4.21, 20.09)	
p-value [3]		0.258		0.181	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	53	120	8	9	
Mean (StdDev)	43.61 (9.906)	43.19 (10.827)	39.59 (10.282)	48.38 (8.111)	
Median	45.68	45.68	36.55	45.68	
Min, Max	27.4, 63.9	15.3, 63.9	27.4, 57.8	39.6, 63.9	
C6D1 CFB					
n	50	114	8	9	
LS Mean (StdErr) [2]	1.70 (1.390)	4.06 (0.968)	2.18 (3.579)	7.35 (4.817)	
95% CI [2]	-1.05, 4.44	2.14, 5.97	-5.55, 9.91	-3.06, 17.76	
Difference (95% CI) in CFB [2]		2.36 (-0.62, 5.34)		5.17 (-3.36, 13.70)	
p-value [3]		0.120		0.213	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	42.75 (11.138)	43.89 (11.915)	44.46 (10.259)	45.68 (7.965)	
Median	45.68	45.68	42.64	45.68	
Min, Max	15.3, 63.9	15.3, 63.9	27.4, 63.9	33.5, 57.8	
C7D1 CFB					
n	49	113	10	8	
LS Mean (StdErr) [2]	0.79 (1.648)	4.08 (1.144)	6.95 (3.830)	9.12 (5.067)	
95% CI [2]	-2.46, 4.05	1.82, 6.34	-1.26, 15.17	-1.74, 19.99	
Difference (95% CI) in CFB [2]		3.29 (-0.19, 6.77)		2.17 (-6.04, 10.39)	
Hedges'G (95% CI) in CFB		0.27 (-0.06, 0.62)		0.16 (-0.83, 1.19)	
p-value [3]		0.064		0.580	
					0.956

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	56	125	11	9	
Mean (StdDev)	32.67 (10.549)	33.77 (10.959)	41.23 (8.746)	34.69 (8.470)	
Median	31.28	33.46	42.94	33.28	
Min, Max	13.8, 60.4	10.5, 61.8	29.7, 56.2	23.5, 51.5	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	35.11 (10.673)	37.65 (12.161)	44.34 (9.259)	38.76 (11.501)	
Median	34.97	38.72	46.30	39.53	
Min, Max	16.5, 61.2	13.0, 58.5	29.3, 60.0	19.0, 56.1	
C2D1 CFB					
n	54	122	11	9	
LS Mean (StdErr) [2]	0.91 (1.034)	2.49 (0.740)	1.19 (3.187)	1.16 (4.042)	
95% CI [2]	-1.13, 2.95	1.02, 3.95	-5.56, 7.95	-7.41, 9.72	
Difference (95% CI) in CFB [2]		1.57 (-0.64, 3.79)		-0.04 (-6.34, 6.26)	
p-value [3]		0.163		0.990	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	119	10	9	
Mean (StdDev)	35.13 (10.112)	38.68 (12.280)	42.10 (9.039)	39.92 (10.694)	
Median	34.87	39.60	43.14	39.25	
Min, Max	15.1, 62.6	13.3, 61.4	29.4, 60.0	20.8, 53.2	
C3D1 CFB					
n	53	115	10	9	
LS Mean (StdErr) [2]	1.92 (1.056)	4.37 (0.749)	0.61 (3.095)	4.74 (3.897)	
95% CI [2]	-0.17, 4.00	2.89, 5.85	-5.98, 7.21	-3.57, 13.04	
Difference (95% CI) in CFB [2]		2.45 (0.18, 4.73)		4.12 (-2.06, 10.31)	
p-value [3]		0.035		0.175	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	117	7	9	
Mean (StdDev)	35.91 (10.380)	38.91 (11.724)	42.13 (11.463)	40.13 (10.851)	
Median	36.16	40.52	42.66	43.45	
Min, Max	10.8, 61.5	12.8, 59.8	26.6, 56.5	23.2, 54.5	
C4D1 CFB					
n	49	112	7	9	
LS Mean (StdErr) [2]	2.58 (1.191)	4.14 (0.858)	-1.24 (3.683)	6.29 (4.910)	
95% CI [2]	0.23, 4.93	2.45, 5.84	-9.27, 6.78	-4.40, 16.99	
Difference (95% CI) in CFB [2]		1.56 (-0.94, 4.07)		7.54 (-1.41, 16.49)	
p-value [3]		0.218		0.091	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	117	9	8	
Mean (StdDev)	36.06 (11.212)	38.78 (12.184)	40.19 (10.893)	40.62 (11.711)	
Median	37.29	38.81	40.79	41.26	
Min, Max	13.5, 60.1	13.0, 64.3	26.8, 53.1	24.8, 53.6	
C5D1 CFB					
n	52	110	9	8	
LS Mean (StdErr) [2]	2.61 (1.132)	4.59 (0.818)	-1.82 (4.381)	3.45 (5.679)	
95% CI [2]	0.37, 4.85	2.98, 6.21	-11.28, 7.65	-8.82, 15.72	
Difference (95% CI) in CFB [2]		1.99 (-0.44, 4.41)		5.27 (-4.29, 14.83)	
p-value [3]		0.107		0.255	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	53	120	8	9	
Mean (StdDev)	35.00 (11.073)	40.45 (11.988)	40.30 (10.790)	40.44 (10.984)	
Median	33.92	41.78	41.12	40.94	
Min, Max	16.4, 58.8	17.3, 61.0	28.1, 58.1	22.7, 54.5	
C6D1 CFB					
n	50	113	8	9	
LS Mean (StdErr) [2]	1.41 (1.203)	5.65 (0.846)	-1.68 (3.223)	4.05 (4.337)	
95% CI [2]	-0.97, 3.79	3.98, 7.32	-8.65, 5.28	-5.32, 13.42	
Difference (95% CI) in CFB [2]		4.24 (1.66, 6.82)		5.74 (-1.94, 13.42)	
p-value [3]		0.001		0.131	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	36.80 (10.942)	39.93 (12.422)	41.22 (10.800)	39.05 (9.910)	
Median	37.20	39.60	38.61	38.54	
Min, Max	14.5, 63.2	12.5, 63.1	27.1, 57.1	23.4, 55.1	
C7D1 CFB					
n	49	112	10	8	
LS Mean (StdErr) [2]	2.48 (1.254)	4.38 (0.879)	-3.00 (4.048)	-1.42 (5.354)	
95% CI [2]	-0.00, 4.95	2.64, 6.11	-11.68, 5.68	-12.91, 10.06	
Difference (95% CI) in CFB [2]		1.90 (-0.75, 4.55)		1.58 (-7.10, 10.26)	
Hedges'G (95% CI) in CFB		0.21 (-0.13, 0.55)		0.11 (-0.88, 1.13)	
p-value [3]		0.158		0.702	
					0.523

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
Baseline					
n	56	125	11	9	
Mean (StdDev)	40.87 (10.776)	40.40 (10.565)	41.61 (10.556)	43.38 (9.872)	
Median	39.30	40.86	42.89	40.96	
Min, Max	19.2, 63.9	13.2, 63.9	26.8, 57.5	33.6, 64.0	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C2D1					
n	58	128	11	9	
Mean (StdDev)	42.70 (10.680)	42.46 (10.513)	41.89 (12.617)	43.81 (8.897)	
Median	42.43	42.71	41.51	40.96	
Min, Max	19.9, 64.4	19.0, 64.8	23.2, 58.2	35.1, 58.5	
C2D1 CFB					
n	54	122	11	9	
LS Mean (StdErr) [2]	2.17 (1.197)	2.92 (0.856)	-0.35 (3.107)	0.26 (3.940)	
95% CI [2]	-0.19, 4.53	1.23, 4.61	-6.94, 6.24	-8.10, 8.61	
Difference (95% CI) in CFB [2]		0.75 (-1.82, 3.32)		0.61 (-5.53, 6.75)	
p-value [3]		0.565		0.837	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C3D1					
n	57	119	10	9	
Mean (StdDev)	43.92 (10.877)	42.88 (10.636)	43.12 (11.091)	49.45 (7.656)	
Median	44.18	45.09	43.86	50.09	
Min, Max	11.2, 63.3	13.8, 66.0	28.6, 61.6	36.5, 60.2	
C3D1 CFB					
n	53	115	10	9	
LS Mean (StdErr) [2]	3.28 (1.232)	3.35 (0.874)	-0.27 (3.541)	3.56 (4.458)	
95% CI [2]	0.85, 5.71	1.62, 5.08	-7.82, 7.27	-5.94, 13.06	
Difference (95% CI) in CFB [2]		0.07 (-2.58, 2.72)		3.83 (-3.24, 10.90)	
p-value [3]		0.960		0.266	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C4D1					
n	53	117	7	9	
Mean (StdDev)	42.84 (9.906)	43.78 (10.688)	38.57 (11.296)	51.04 (10.017)	
Median	41.23	44.78	36.48	53.83	
Min, Max	22.0, 59.7	13.7, 63.9	22.1, 55.7	31.0, 60.9	
C4D1 CFB					
n	49	112	7	9	
LS Mean (StdErr) [2]	2.79 (1.442)	4.15 (1.039)	-0.50 (4.607)	4.83 (6.142)	
95% CI [2]	-0.05, 5.64	2.10, 6.21	-10.54, 9.54	-8.55, 18.21	
Difference (95% CI) in CFB [2]		1.36 (-1.67, 4.39)		5.33 (-5.86, 16.53)	
p-value [3]		0.376		0.320	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C5D1					
n	55	117	9	8	
Mean (StdDev)	44.31 (11.439)	44.15 (10.402)	36.00 (10.772)	51.66 (10.054)	
Median	46.36	45.02	38.48	55.84	
Min, Max	14.1, 61.6	19.5, 64.4	18.6, 54.6	31.4, 60.4	
C5D1 CFB					
n	52	110	9	8	
LS Mean (StdErr) [2]	3.40 (1.418)	4.15 (1.024)	-1.53 (6.552)	7.89 (8.493)	
95% CI [2]	0.60, 6.20	2.13, 6.17	-15.68, 12.63	-10.45, 26.24	
Difference (95% CI) in CFB [2]		0.75 (-2.28, 3.78)		9.42 (-4.88, 23.71)	
p-value [3]		0.626		0.178	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C6D1					
n	53	120	8	9	
Mean (StdDev)	43.98 (10.713)	43.30 (10.908)	39.25 (8.892)	51.43 (7.109)	
Median	43.94	44.54	37.34	51.51	
Min, Max	24.1, 61.4	12.1, 61.5	29.6, 55.6	39.6, 60.4	
C6D1 CFB					
n	50	113	8	9	
LS Mean (StdErr) [2]	2.80 (1.492)	3.33 (1.049)	-0.05 (3.128)	4.43 (4.211)	
95% CI [2]	-0.15, 5.74	1.26, 5.40	-6.81, 6.71	-4.67, 13.53	
Difference (95% CI) in CFB [2]		0.53 (-2.66, 3.73)		4.48 (-2.97, 11.94)	
p-value [3]		0.742		0.217	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.1a
Change from Baseline of SF-12 by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Age <65 years		Age >=65 years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	Test of Interaction p-value [1]
C7D1					
n	52	119	10	8	
Mean (StdDev)	42.84 (11.733)	44.03 (11.449)	44.66 (10.493)	47.44 (9.601)	
Median	42.90	44.70	45.48	49.69	
Min, Max	12.1, 64.6	12.0, 63.3	31.2, 64.9	33.3, 60.7	
C7D1 CFB					
n	49	112	10	8	
LS Mean (StdErr) [2]	1.22 (1.530)	3.70 (1.073)	5.98 (3.766)	8.75 (4.981)	
95% CI [2]	-1.80, 4.25	1.58, 5.81	-2.09, 14.06	-1.94, 19.43	
Difference (95% CI) in CFB [2]		2.47 (-0.76, 5.71)		2.77 (-5.31, 10.84)	
Hedges'G (95% CI) in CFB		0.22 (-0.12, 0.56)		0.20 (-0.77, 1.24)	
p-value [3]		0.133		0.475	
					0.897

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-age-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	51	98	
Mean (StdDev)	38.63 (10.587)	40.82 (12.411)	37.87 (12.628)	36.17 (10.935)	
Median	39.69	39.69	39.69	35.48	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	40.74 (11.024)	44.43 (11.386)	40.16 (11.242)	39.17 (11.949)	
Median	39.69	48.10	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C2D1 CFB					
n	15	36	50	96	
LS Mean (StdErr) [2]	2.04 (1.873)	3.33 (1.260)	1.36 (1.224)	1.97 (0.972)	
95% CI [2]	-1.73, 5.80	0.80, 5.87	-1.06, 3.78	0.05, 3.89	
Difference (95% CI) in CFB [2]		1.30 (-2.90, 5.49)		0.61 (-1.99, 3.20)	
p-value [3]		0.537		0.644	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	94	
Mean (StdDev)	38.70 (8.866)	44.39 (11.753)	40.02 (11.011)	39.86 (12.025)	
Median	39.69	39.69	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C3D1 CFB					
n	16	33	47	92	
LS Mean (StdErr) [2]	0.57 (1.967)	3.92 (1.412)	1.76 (1.297)	3.10 (0.993)	
95% CI [2]	-3.39, 4.54	1.08, 6.76	-0.81, 4.32	1.14, 5.07	
Difference (95% CI) in CFB [2]		3.34 (-1.11, 7.80)		1.35 (-1.40, 4.09)	
p-value [3]		0.137		0.334	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	39.69 (6.360)	44.36 (11.279)	39.87 (12.099)	40.32 (11.653)	
Median	39.69	43.89	39.69	39.69	
Min, Max	31.3, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C4D1 CFB					
n	14	34	42	91	
LS Mean (StdErr) [2]	5.01 (2.029)	5.36 (1.423)	1.75 (1.528)	3.81 (1.146)	
95% CI [2]	0.93, 9.10	2.49, 8.23	-1.27, 4.78	1.54, 6.08	
Difference (95% CI) in CFB [2]		0.34 (-4.19, 4.88)		2.06 (-1.11, 5.23)	
p-value [3]		0.880		0.202	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	89	
Mean (StdDev)	41.17 (11.986)	44.83 (11.427)	40.04 (12.276)	40.44 (11.739)	
Median	39.69	48.10	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C5D1 CFB					
n	16	32	45	87	
LS Mean (StdErr) [2]	3.32 (1.996)	4.29 (1.480)	1.32 (1.503)	4.27 (1.156)	
95% CI [2]	-0.70, 7.34	1.31, 7.28	-1.66, 4.29	1.98, 6.55	
Difference (95% CI) in CFB [2]		0.98 (-3.51, 5.46)		2.95 (-0.25, 6.15)	
p-value [3]		0.663		0.071	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	37.44 (6.721)	45.66 (11.050)	39.86 (12.466)	41.26 (12.474)	
Median	39.69	48.10	39.69	39.69	
Min, Max	31.3, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C6D1 CFB					
n	14	34	45	89	
LS Mean (StdErr) [2]	1.52 (2.256)	5.57 (1.535)	0.60 (1.438)	4.40 (1.101)	
95% CI [2]	-3.02, 6.07	2.47, 8.66	-2.24, 3.45	2.22, 6.58	
Difference (95% CI) in CFB [2]		4.04 (-1.02, 9.10)		3.80 (0.73, 6.87)	
p-value [3]		0.115		0.016	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	38.63 (9.153)	44.11 (11.020)	40.42 (12.008)	41.29 (12.803)	
Median	39.69	39.69	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C7D1 CFB					
n	15	34	44	87	
LS Mean (StdErr) [2]	1.20 (2.709)	4.39 (1.888)	0.35 (1.597)	3.43 (1.220)	
95% CI [2]	-4.25, 6.66	0.58, 8.19	-2.81, 3.51	1.01, 5.84	
Difference (95% CI) in CFB [2]		3.18 (-2.89, 9.25)		3.08 (-0.25, 6.41)	
Hedges'G (95% CI) in CFB		0.29 (-0.32, 0.93)		0.28 (-0.09, 0.65)	
p-value [3]		0.297		0.069	
					0.942

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	51	98	
Mean (StdDev)	34.51 (5.911)	37.55 (8.729)	34.60 (8.302)	33.74 (8.455)	
Median	34.51	39.00	34.51	34.51	
Min, Max	25.5, 48.0	21.0, 57.0	21.0, 52.5	21.0, 57.0	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	33.67 (6.997)	39.23 (9.493)	37.23 (9.857)	36.99 (10.317)	
Median	34.51	39.00	39.00	34.51	
Min, Max	21.0, 48.0	21.0, 57.0	21.0, 57.0	21.0, 57.0	
C2D1 CFB					
n	15	36	50	96	
LS Mean (StdErr) [2]	-1.52 (1.791)	1.11 (1.205)	1.61 (1.167)	2.16 (0.927)	
95% CI [2]	-5.12, 2.09	-1.32, 3.53	-0.70, 3.92	0.33, 4.00	
Difference (95% CI) in CFB [2]		2.62 (-1.39, 6.63)		0.56 (-1.92, 3.03)	
p-value [3]		0.195		0.658	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	94	
Mean (StdDev)	36.36 (8.702)	42.44 (9.251)	36.94 (10.068)	38.05 (10.386)	
Median	39.00	45.74	34.51	39.00	
Min, Max	21.0, 48.0	21.0, 57.0	21.0, 57.0	21.0, 57.0	
C3D1 CFB					
n	16	33	47	92	
LS Mean (StdErr) [2]	1.31 (2.191)	4.44 (1.572)	1.41 (1.243)	3.68 (0.952)	
95% CI [2]	-3.11, 5.72	1.27, 7.60	-1.05, 3.87	1.79, 5.56	
Difference (95% CI) in CFB [2]		3.13 (-1.83, 8.09)		2.27 (-0.36, 4.90)	
p-value [3]		0.210		0.091	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	91	
Mean (StdDev)	34.81 (6.886)	41.00 (8.878)	37.61 (10.863)	39.50 (10.780)	
Median	34.51	41.25	39.00	39.00	
Min, Max	25.5, 52.5	25.5, 57.0	21.0, 57.0	21.0, 57.0	
C4D1 CFB					
n	14	34	42	89	
LS Mean (StdErr) [2]	1.58 (1.877)	4.14 (1.317)	2.34 (1.446)	4.76 (1.097)	
95% CI [2]	-2.21, 5.36	1.48, 6.79	-0.52, 5.20	2.59, 6.94	
Difference (95% CI) in CFB [2]		2.56 (-1.64, 6.76)		2.42 (-0.58, 5.42)	
p-value [3]		0.226		0.113	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	89	
Mean (StdDev)	37.16 (8.846)	41.12 (8.750)	37.19 (9.668)	39.00 (10.485)	
Median	39.00	39.00	39.00	39.00	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 57.0	21.0, 57.0	
C5D1 CFB					
n	16	32	45	87	
LS Mean (StdErr) [2]	3.11 (1.979)	3.70 (1.467)	1.80 (1.330)	5.00 (1.023)	
95% CI [2]	-0.88, 7.10	0.74, 6.66	-0.84, 4.43	2.97, 7.02	
Difference (95% CI) in CFB [2]		0.59 (-3.86, 5.04)		3.20 (0.37, 6.03)	
p-value [3]		0.790		0.027	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	35.41 (6.830)	41.37 (9.262)	36.33 (10.741)	40.58 (10.653)	
Median	34.51	39.00	34.51	39.00	
Min, Max	25.5, 52.5	21.0, 57.0	21.0, 57.0	21.0, 57.0	
C6D1 CFB					
n	14	34	45	89	
LS Mean (StdErr) [2]	1.73 (2.241)	3.93 (1.525)	0.58 (1.417)	5.63 (1.085)	
95% CI [2]	-2.79, 6.24	0.85, 7.00	-2.22, 3.39	3.48, 7.77	
Difference (95% CI) in CFB [2]		2.20 (-2.83, 7.23)		5.04 (2.02, 8.06)	
p-value [3]		0.383		0.001	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	36.48 (9.694)	41.13 (9.143)	38.52 (10.717)	40.27 (11.365)	
Median	34.51	39.00	39.00	39.00	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 57.0	21.0, 57.0	
C7D1 CFB					
n	15	34	44	87	
LS Mean (StdErr) [2]	2.26 (2.405)	3.32 (1.676)	2.49 (1.530)	5.29 (1.169)	
95% CI [2]	-2.59, 7.10	-0.06, 6.70	-0.54, 5.52	2.98, 7.61	
Difference (95% CI) in CFB [2]		1.06 (-4.33, 6.45)		2.80 (-0.39, 5.99)	
Hedges'G (95% CI) in CFB		0.11 (-0.51, 0.74)		0.26 (-0.10, 0.63)	
p-value [3]		0.693		0.085	
					0.598

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	51	97	
Mean (StdDev)	33.06 (11.074)	36.27 (11.610)	32.24 (10.884)	30.66 (11.292)	
Median	36.27	36.27	26.00	26.00	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	37.55 (10.524)	39.96 (11.419)	35.30 (11.617)	37.95 (12.999)	
Median	36.27	46.54	36.27	36.27	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C2D1 CFB					
n	15	36	50	95	
LS Mean (StdErr) [2]	3.78 (2.466)	2.58 (1.659)	0.99 (1.636)	5.65 (1.314)	
95% CI [2]	-1.18, 8.74	-0.76, 5.91	-2.24, 4.22	3.05, 8.25	
Difference (95% CI) in CFB [2]		-1.20 (-6.72, 4.32)		4.66 (1.19, 8.13)	
p-value [3]		0.664		0.009	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	94	
Mean (StdDev)	38.08 (12.701)	41.71 (11.923)	36.27 (10.782)	38.89 (12.043)	
Median	36.27	46.54	36.27	36.27	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C3D1 CFB					
n	16	33	47	91	
LS Mean (StdErr) [2]	4.07 (2.366)	4.87 (1.699)	3.69 (1.540)	8.29 (1.193)	
95% CI [2]	-0.70, 8.83	1.45, 8.29	0.65, 6.74	5.93, 10.65	
Difference (95% CI) in CFB [2]		0.80 (-4.55, 6.16)		4.60 (1.34, 7.87)	
p-value [3]		0.764		0.006	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	92	
Mean (StdDev)	38.32 (9.666)	41.12 (10.556)	35.58 (11.036)	38.39 (13.407)	
Median	36.27	46.54	36.27	36.27	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C4D1 CFB					
n	14	34	42	89	
LS Mean (StdErr) [2]	5.83 (2.894)	4.43 (2.030)	1.52 (1.791)	6.36 (1.387)	
95% CI [2]	-0.00, 11.66	0.34, 8.53	-2.03, 5.06	3.62, 9.11	
Difference (95% CI) in CFB [2]		-1.40 (-7.87, 5.08)		4.85 (1.16, 8.54)	
p-value [3]		0.666		0.010	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	89	
Mean (StdDev)	37.48 (11.415)	42.54 (10.779)	35.61 (12.377)	37.88 (13.666)	
Median	36.27	46.54	36.27	36.27	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C5D1 CFB					
n	16	32	45	86	
LS Mean (StdErr) [2]	2.78 (2.741)	4.23 (2.032)	2.14 (1.776)	7.01 (1.381)	
95% CI [2]	-2.74, 8.31	0.14, 8.33	-1.38, 5.65	4.28, 9.74	
Difference (95% CI) in CFB [2]		1.45 (-4.71, 7.62)		4.87 (1.09, 8.65)	
p-value [3]		0.638		0.012	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	46	91	
Mean (StdDev)	34.90 (12.193)	41.13 (11.386)	35.60 (13.064)	39.99 (13.480)	
Median	36.27	46.54	36.27	46.54	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C6D1 CFB					
n	14	34	44	88	
LS Mean (StdErr) [2]	1.46 (2.742)	3.66 (1.866)	1.97 (1.755)	8.57 (1.354)	
95% CI [2]	-4.07, 6.98	-0.10, 7.43	-1.51, 5.44	5.89, 11.25	
Difference (95% CI) in CFB [2]		2.21 (-3.95, 8.36)		6.60 (2.85, 10.35)	
p-value [3]		0.474		<0.001	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	37.55 (9.833)	41.13 (12.114)	37.83 (12.049)	39.04 (14.001)	
Median	36.27	46.54	36.27	36.27	
Min, Max	26.0, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C7D1 CFB					
n	15	34	44	86	
LS Mean (StdErr) [2]	2.90 (2.586)	2.92 (1.802)	2.42 (1.851)	5.72 (1.433)	
95% CI [2]	-2.31, 8.10	-0.71, 6.55	-1.25, 6.08	2.88, 8.56	
Difference (95% CI) in CFB [2]		0.02 (-5.77, 5.82)		3.30 (-0.55, 7.16)	
Hedges'G (95% CI) in CFB		0.00 (-0.62, 0.63)		0.25 (-0.11, 0.63)	
p-value [3]		0.993		0.092	
					0.374

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	51	98	
Mean (StdDev)	30.84 (8.132)	36.48 (10.769)	34.75 (10.919)	32.82 (9.021)	
Median	30.05	30.05	30.05	30.05	
Min, Max	19.4, 44.9	19.4, 55.5	19.4, 61.9	19.4, 55.5	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	33.37 (8.776)	39.03 (10.882)	37.06 (11.362)	34.51 (10.410)	
Median	30.05	44.92	30.05	30.05	
Min, Max	19.4, 44.9	19.4, 55.5	19.4, 55.5	19.4, 55.5	
C2D1 CFB					
n	15	36	50	96	
LS Mean (StdErr) [2]	1.28 (1.816)	2.36 (1.221)	1.66 (1.425)	1.43 (1.132)	
95% CI [2]	-2.37, 4.93	-0.09, 4.82	-1.16, 4.48	-0.80, 3.67	
Difference (95% CI) in CFB [2]		1.09 (-2.98, 5.15)		-0.23 (-3.25, 2.80)	
p-value [3]		0.593		0.882	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	94	
Mean (StdDev)	31.42 (7.319)	38.86 (10.605)	36.46 (10.518)	36.89 (11.200)	
Median	30.05	44.92	30.05	30.05	
Min, Max	19.4, 44.9	19.4, 55.5	19.4, 55.5	19.4, 61.9	
C3D1 CFB					
n	16	33	47	92	
LS Mean (StdErr) [2]	-0.27 (1.970)	2.41 (1.414)	0.25 (1.558)	3.42 (1.193)	
95% CI [2]	-4.24, 3.70	-0.43, 5.26	-2.83, 3.33	1.06, 5.78	
Difference (95% CI) in CFB [2]		2.69 (-1.77, 7.14)		3.18 (-0.12, 6.48)	
p-value [3]		0.231		0.059	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	32.59 (8.506)	40.73 (10.390)	37.13 (11.141)	36.28 (11.052)	
Median	30.05	44.92	30.05	30.05	
Min, Max	19.4, 44.9	19.4, 55.5	19.4, 61.9	19.4, 55.5	
C4D1 CFB					
n	14	34	42	91	
LS Mean (StdErr) [2]	-0.36 (2.896)	4.19 (2.031)	1.25 (1.564)	2.04 (1.173)	
95% CI [2]	-6.20, 5.47	0.10, 8.28	-1.84, 4.35	-0.28, 4.36	
Difference (95% CI) in CFB [2]		4.55 (-1.92, 11.03)		0.78 (-2.46, 4.03)	
p-value [3]		0.163		0.634	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	89	
Mean (StdDev)	34.42 (9.091)	41.61 (10.439)	37.01 (10.453)	36.56 (10.656)	
Median	30.05	44.92	30.05	30.05	
Min, Max	19.4, 55.5	19.4, 55.5	19.4, 61.9	19.4, 55.5	
C5D1 CFB					
n	16	32	45	87	
LS Mean (StdErr) [2]	3.02 (2.544)	4.48 (1.886)	1.51 (1.610)	3.51 (1.238)	
95% CI [2]	-2.11, 8.15	0.68, 8.28	-1.67, 4.70	1.06, 5.96	
Difference (95% CI) in CFB [2]		1.46 (-4.26, 7.18)		2.00 (-1.43, 5.43)	
p-value [3]		0.610		0.251	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	34.29 (8.228)	41.79 (10.180)	36.87 (12.018)	37.47 (11.186)	
Median	30.05	44.92	44.92	44.92	
Min, Max	19.4, 44.9	19.4, 55.5	19.4, 61.9	19.4, 55.5	
C6D1 CFB					
n	14	34	45	89	
LS Mean (StdErr) [2]	1.85 (2.730)	4.98 (1.858)	1.40 (1.545)	4.21 (1.184)	
95% CI [2]	-3.65, 7.35	1.23, 8.72	-1.66, 4.46	1.86, 6.55	
Difference (95% CI) in CFB [2]		3.13 (-3.00, 9.25)		2.81 (-0.49, 6.10)	
p-value [3]		0.309		0.094	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	34.03 (8.020)	41.23 (9.676)	37.57 (11.608)	38.07 (11.377)	
Median	30.05	44.92	44.92	44.92	
Min, Max	19.4, 44.9	19.4, 55.5	19.4, 55.5	19.4, 55.5	
C7D1 CFB					
n	15	34	44	87	
LS Mean (StdErr) [2]	1.58 (2.630)	4.74 (1.833)	0.53 (1.675)	3.68 (1.280)	
95% CI [2]	-3.72, 6.88	1.05, 8.43	-2.78, 3.85	1.15, 6.22	
Difference (95% CI) in CFB [2]		3.16 (-2.73, 9.05)		3.15 (-0.34, 6.64)	
Hedges'G (95% CI) in CFB		0.30 (-0.32, 0.94)		0.27 (-0.09, 0.64)	
p-value [3]		0.285		0.076	
					0.968

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	51	98	
Mean (StdDev)	37.64 (8.329)	38.51 (8.750)	39.97 (9.089)	37.25 (8.225)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 48.0	28.5, 57.8	28.5, 57.8	28.5, 57.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	40.69 (9.080)	39.50 (9.800)	40.83 (9.003)	40.14 (9.464)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 67.5	28.5, 57.8	
C2D1 CFB					
n	15	36	50	96	
LS Mean (StdErr) [2]	2.31 (1.391)	1.11 (0.936)	1.00 (1.402)	3.32 (1.114)	
95% CI [2]	-0.49, 5.11	-0.77, 3.00	-1.78, 3.77	1.12, 5.53	
Difference (95% CI) in CFB [2]		-1.20 (-4.31, 1.92)		2.33 (-0.65, 5.30)	
p-value [3]		0.443		0.124	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	94	
Mean (StdDev)	38.82 (6.424)	42.27 (9.935)	42.54 (10.270)	40.32 (9.793)	
Median	38.25	38.25	48.00	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 67.5	28.5, 57.8	
C3D1 CFB					
n	16	33	47	92	
LS Mean (StdErr) [2]	0.20 (1.718)	3.34 (1.233)	3.20 (1.407)	3.50 (1.078)	
95% CI [2]	-3.27, 3.66	0.86, 5.83	0.41, 5.98	1.37, 5.63	
Difference (95% CI) in CFB [2]		3.15 (-0.74, 7.04)		0.30 (-2.68, 3.28)	
p-value [3]		0.110		0.842	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	37.60 (7.791)	41.77 (9.934)	41.07 (8.730)	40.87 (10.384)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 48.0	28.5, 57.8	28.5, 57.8	28.5, 57.8	
C4D1 CFB					
n	14	34	42	91	
LS Mean (StdErr) [2]	-0.18 (2.018)	2.21 (1.416)	1.78 (1.728)	3.38 (1.296)	
95% CI [2]	-4.25, 3.89	-0.64, 5.06	-1.64, 5.19	0.81, 5.94	
Difference (95% CI) in CFB [2]		2.39 (-2.12, 6.90)		1.60 (-1.98, 5.19)	
p-value [3]		0.292		0.378	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	89	
Mean (StdDev)	40.54 (10.645)	42.58 (9.738)	40.74 (8.974)	41.10 (10.103)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 57.8	28.5, 67.5	
C5D1 CFB					
n	16	32	45	87	
LS Mean (StdErr) [2]	2.38 (1.816)	3.91 (1.346)	1.18 (1.705)	3.72 (1.311)	
95% CI [2]	-1.28, 6.04	1.20, 6.63	-2.19, 4.56	1.12, 6.31	
Difference (95% CI) in CFB [2]		1.54 (-2.55, 5.62)		2.54 (-1.09, 6.17)	
p-value [3]		0.452		0.169	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	38.90 (8.620)	41.59 (9.426)	39.49 (9.235)	43.07 (10.217)	
Median	38.25	38.25	38.25	48.00	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 57.8	28.5, 67.5	
C6D1 CFB					
n	14	34	45	89	
LS Mean (StdErr) [2]	2.39 (1.864)	3.00 (1.268)	-0.34 (1.577)	5.31 (1.208)	
95% CI [2]	-1.36, 6.15	0.44, 5.55	-3.46, 2.78	2.92, 7.70	
Difference (95% CI) in CFB [2]		0.61 (-3.58, 4.79)		5.66 (2.29, 9.02)	
p-value [3]		0.772		0.001	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	40.08 (10.211)	41.84 (8.905)	42.07 (10.581)	42.19 (10.976)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 67.5	28.5, 67.5	
C7D1 CFB					
n	15	34	44	87	
LS Mean (StdErr) [2]	2.88 (1.865)	4.04 (1.300)	2.55 (1.681)	4.25 (1.285)	
95% CI [2]	-0.88, 6.63	1.42, 6.65	-0.78, 5.87	1.70, 6.79	
Difference (95% CI) in CFB [2]		1.16 (-3.02, 5.34)		1.70 (-1.80, 5.21)	
Hedges'G (95% CI) in CFB		0.15 (-0.46, 0.78)		0.14 (-0.22, 0.51)	
p-value [3]		0.579		0.338	
					0.826

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	51	98	
Mean (StdDev)	35.67 (11.713)	41.64 (9.519)	37.45 (11.838)	36.18 (11.433)	
Median	36.29	36.29	36.29	36.29	
Min, Max	16.5, 56.1	26.4, 56.1	16.5, 56.1	16.5, 56.1	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	40.00 (10.785)	41.88 (10.119)	39.84 (11.015)	40.53 (11.825)	
Median	41.24	46.20	36.29	41.24	
Min, Max	16.5, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C2D1 CFB					
n	15	36	50	96	
LS Mean (StdErr) [2]	2.72 (2.244)	-0.49 (1.509)	2.07 (1.702)	4.30 (1.352)	
95% CI [2]	-1.80, 7.23	-3.53, 2.55	-1.29, 5.44	1.63, 6.97	
Difference (95% CI) in CFB [2]		-3.21 (-8.23, 1.81)		2.23 (-1.38, 5.84)	
p-value [3]		0.205		0.224	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	94	
Mean (StdDev)	43.28 (11.500)	45.62 (8.434)	40.05 (11.132)	39.13 (12.304)	
Median	46.20	46.20	36.29	36.29	
Min, Max	16.5, 56.1	26.4, 56.1	16.5, 56.1	16.5, 56.1	
C3D1 CFB					
n	16	33	47	92	
LS Mean (StdErr) [2]	6.68 (2.496)	3.99 (1.792)	2.64 (1.583)	2.61 (1.212)	
95% CI [2]	1.66, 11.71	0.38, 7.60	-0.49, 5.77	0.21, 5.00	
Difference (95% CI) in CFB [2]		-2.70 (-8.35, 2.95)		-0.03 (-3.38, 3.32)	
p-value [3]		0.342		0.985	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	42.23 (11.116)	44.00 (10.360)	38.71 (11.015)	40.44 (12.770)	
Median	46.20	46.20	36.29	46.20	
Min, Max	26.4, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C4D1 CFB					
n	14	34	42	91	
LS Mean (StdErr) [2]	5.03 (2.804)	3.29 (1.967)	0.85 (1.870)	3.46 (1.403)	
95% CI [2]	-0.62, 10.68	-0.67, 7.26	-2.85, 4.55	0.68, 6.23	
Difference (95% CI) in CFB [2]		-1.74 (-8.01, 4.53)		2.60 (-1.28, 6.49)	
p-value [3]		0.579		0.187	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	89	
Mean (StdDev)	41.53 (10.584)	46.75 (10.315)	39.03 (12.352)	41.63 (12.239)	
Median	36.29	46.20	36.29	46.20	
Min, Max	26.4, 56.1	26.4, 56.1	16.5, 56.1	16.5, 56.1	
C5D1 CFB					
n	16	32	45	87	
LS Mean (StdErr) [2]	3.12 (2.282)	3.73 (1.692)	1.50 (1.958)	5.93 (1.506)	
95% CI [2]	-1.48, 7.72	0.32, 7.14	-2.38, 5.37	2.95, 8.91	
Difference (95% CI) in CFB [2]		0.60 (-4.53, 5.74)		4.43 (0.26, 8.60)	
p-value [3]		0.814		0.037	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	40.91 (11.158)	44.90 (10.092)	38.61 (11.733)	41.73 (12.650)	
Median	36.29	46.20	36.29	46.20	
Min, Max	26.4, 56.1	26.4, 56.1	16.5, 56.1	16.5, 56.1	
C6D1 CFB					
n	14	34	45	89	
LS Mean (StdErr) [2]	3.88 (2.380)	3.41 (1.620)	0.50 (2.000)	4.66 (1.532)	
95% CI [2]	-0.92, 8.67	0.14, 6.67	-3.46, 4.45	1.63, 7.69	
Difference (95% CI) in CFB [2]		-0.47 (-5.81, 4.87)		4.16 (-0.10, 8.42)	
p-value [3]		0.860		0.056	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	41.86 (12.524)	45.16 (8.864)	40.17 (11.726)	41.74 (13.369)	
Median	36.29	46.20	36.29	46.20	
Min, Max	26.4, 56.1	26.4, 56.1	16.5, 56.1	16.5, 56.1	
C7D1 CFB					
n	15	34	44	87	
LS Mean (StdErr) [2]	4.49 (2.459)	3.69 (1.714)	0.97 (2.071)	4.61 (1.583)	
95% CI [2]	-0.47, 9.44	0.23, 7.14	-3.12, 5.07	1.48, 7.75	
Difference (95% CI) in CFB [2]		-0.80 (-6.31, 4.71)		3.64 (-0.68, 7.95)	
Hedges'G (95% CI) in CFB		-0.08 (-0.71, 0.54)		0.25 (-0.11, 0.62)	
p-value [3]		0.771		0.098	
					0.267

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	51	98	
Mean (StdDev)	39.27 (11.577)	40.91 (11.255)	36.89 (12.104)	37.19 (11.874)	
Median	36.51	39.27	33.75	36.51	
Min, Max	22.7, 55.8	17.2, 55.8	11.7, 55.8	11.7, 55.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	38.93 (11.831)	42.95 (11.627)	40.52 (11.229)	41.07 (11.695)	
Median	36.51	44.79	39.27	44.79	
Min, Max	22.7, 55.8	11.7, 55.8	17.2, 55.8	11.7, 55.8	
C2D1 CFB					
n	15	36	50	96	
LS Mean (StdErr) [2]	0.76 (2.556)	2.78 (1.719)	4.18 (1.481)	4.54 (1.176)	
95% CI [2]	-4.38, 5.90	-0.68, 6.24	1.25, 7.10	2.22, 6.86	
Difference (95% CI) in CFB [2]		2.02 (-3.70, 7.74)		0.36 (-2.78, 3.50)	
p-value [3]		0.481		0.820	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	94	
Mean (StdDev)	41.87 (13.814)	45.44 (11.102)	40.82 (12.011)	40.62 (11.914)	
Median	44.79	50.31	42.03	42.03	
Min, Max	11.7, 55.8	22.7, 55.8	11.7, 55.8	11.7, 55.8	
C3D1 CFB					
n	16	33	47	92	
LS Mean (StdErr) [2]	2.60 (2.645)	5.31 (1.899)	4.32 (1.590)	4.32 (1.218)	
95% CI [2]	-2.73, 7.92	1.48, 9.13	1.17, 7.47	1.91, 6.72	
Difference (95% CI) in CFB [2]		2.71 (-3.28, 8.70)		-0.00 (-3.37, 3.36)	
p-value [3]		0.367		0.998	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	92	
Mean (StdDev)	41.85 (11.207)	43.87 (10.919)	38.78 (12.274)	42.21 (12.230)	
Median	39.27	44.79	33.75	44.79	
Min, Max	22.7, 55.8	17.2, 55.8	17.2, 55.8	11.7, 55.8	
C4D1 CFB					
n	14	34	42	90	
LS Mean (StdErr) [2]	1.37 (2.640)	2.94 (1.852)	3.72 (1.910)	5.75 (1.433)	
95% CI [2]	-3.95, 6.69	-0.79, 6.67	-0.06, 7.50	2.92, 8.59	
Difference (95% CI) in CFB [2]		1.57 (-4.33, 7.47)		2.03 (-1.94, 6.00)	
p-value [3]		0.595		0.314	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	89	
Mean (StdDev)	41.87 (11.058)	44.94 (9.186)	40.80 (12.590)	42.43 (11.763)	
Median	44.79	44.79	39.27	44.79	
Min, Max	17.2, 55.8	22.7, 55.8	11.7, 55.8	11.7, 55.8	
C5D1 CFB					
n	16	32	45	87	
LS Mean (StdErr) [2]	1.87 (2.348)	2.66 (1.741)	3.85 (1.933)	5.69 (1.486)	
95% CI [2]	-2.86, 6.60	-0.85, 6.17	0.03, 7.67	2.75, 8.63	
Difference (95% CI) in CFB [2]		0.79 (-4.49, 6.07)		1.84 (-2.27, 5.96)	
p-value [3]		0.764		0.377	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	47	91	
Mean (StdDev)	43.32 (9.665)	44.06 (10.279)	40.45 (13.710)	41.82 (12.294)	
Median	44.79	44.79	44.79	44.79	
Min, Max	28.2, 55.8	17.2, 55.8	11.7, 55.8	11.7, 55.8	
C6D1 CFB					
n	14	34	45	89	
LS Mean (StdErr) [2]	3.55 (3.022)	4.12 (2.057)	3.16 (1.983)	4.01 (1.519)	
95% CI [2]	-2.54, 9.64	-0.02, 8.27	-0.76, 7.08	1.00, 7.01	
Difference (95% CI) in CFB [2]		0.57 (-6.21, 7.35)		0.85 (-3.38, 5.07)	
p-value [3]		0.866		0.693	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	42.72 (13.196)	44.79 (10.345)	39.63 (12.607)	41.75 (12.029)	
Median	44.79	44.79	39.27	44.79	
Min, Max	11.7, 55.8	17.2, 55.8	11.7, 55.8	11.7, 55.8	
C7D1 CFB					
n	15	34	44	87	
LS Mean (StdErr) [2]	1.05 (2.439)	3.01 (1.700)	1.19 (1.830)	4.09 (1.399)	
95% CI [2]	-3.86, 5.96	-0.42, 6.43	-2.43, 4.82	1.32, 6.85	
Difference (95% CI) in CFB [2]		1.96 (-3.50, 7.42)		2.89 (-0.92, 6.71)	
Hedges'G (95% CI) in CFB		0.20 (-0.42, 0.83)		0.23 (-0.14, 0.60)	
p-value [3]		0.474		0.136	
					0.764

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	51	98	
Mean (StdDev)	43.02 (10.645)	41.07 (11.051)	40.91 (9.449)	39.35 (9.841)	
Median	39.59	39.59	39.59	39.59	
Min, Max	33.5, 63.9	15.3, 63.9	21.3, 57.8	15.3, 63.9	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	44.54 (11.800)	41.93 (11.305)	41.55 (10.036)	41.64 (10.147)	
Median	42.64	45.68	39.59	39.59	
Min, Max	27.4, 63.9	15.3, 63.9	21.3, 57.8	15.3, 57.8	
C2D1 CFB					
n	15	36	50	96	
LS Mean (StdErr) [2]	0.42 (1.741)	0.69 (1.171)	1.56 (1.184)	3.40 (0.940)	
95% CI [2]	-3.08, 3.93	-1.66, 3.05	-0.78, 3.90	1.54, 5.26	
Difference (95% CI) in CFB [2]		0.27 (-3.63, 4.16)		1.84 (-0.67, 4.35)	
p-value [3]		0.891		0.150	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	94	
Mean (StdDev)	43.53 (12.713)	44.60 (11.353)	42.76 (9.539)	43.22 (10.937)	
Median	45.68	45.68	42.64	45.68	
Min, Max	15.3, 63.9	21.3, 63.9	27.4, 63.9	15.3, 63.9	
C3D1 CFB					
n	16	33	47	92	
LS Mean (StdErr) [2]	-0.42 (2.555)	3.28 (1.834)	2.15 (1.317)	4.56 (1.009)	
95% CI [2]	-5.56, 4.73	-0.41, 6.98	-0.46, 4.75	2.57, 6.56	
Difference (95% CI) in CFB [2]		3.70 (-2.08, 9.48)		2.42 (-0.37, 5.21)	
p-value [3]		0.204		0.089	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	93	
Mean (StdDev)	44.87 (11.232)	44.66 (10.536)	42.03 (9.388)	44.17 (11.045)	
Median	45.68	45.68	39.59	45.68	
Min, Max	27.4, 63.9	21.3, 63.9	21.3, 63.9	15.3, 63.9	
C4D1 CFB					
n	14	34	42	91	
LS Mean (StdErr) [2]	0.77 (2.291)	4.24 (1.607)	3.00 (1.569)	5.71 (1.176)	
95% CI [2]	-3.84, 5.39	1.00, 7.47	-0.11, 6.10	3.38, 8.04	
Difference (95% CI) in CFB [2]		3.46 (-1.66, 8.59)		2.71 (-0.55, 5.96)	
p-value [3]		0.180		0.102	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	89	
Mean (StdDev)	44.60 (12.584)	45.00 (9.731)	42.44 (10.371)	43.42 (10.631)	
Median	45.68	45.68	39.59	45.68	
Min, Max	21.3, 63.9	27.4, 63.9	21.3, 63.9	15.3, 63.9	
C5D1 CFB					
n	16	32	45	87	
LS Mean (StdErr) [2]	0.99 (2.220)	3.43 (1.646)	1.67 (1.574)	4.32 (1.211)	
95% CI [2]	-3.49, 5.46	0.12, 6.75	-1.45, 4.78	1.93, 6.72	
Difference (95% CI) in CFB [2]		2.45 (-2.55, 7.44)		2.65 (-0.70, 6.01)	
p-value [3]		0.329		0.120	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	46	91	
Mean (StdDev)	45.27 (9.880)	44.72 (10.152)	42.37 (9.992)	43.07 (10.962)	
Median	45.68	45.68	39.59	45.68	
Min, Max	33.5, 57.8	15.3, 63.9	27.4, 63.9	15.3, 63.9	
C6D1 CFB					
n	14	34	44	89	
LS Mean (StdErr) [2]	1.10 (2.496)	4.85 (1.699)	1.70 (1.497)	4.20 (1.142)	
95% CI [2]	-3.93, 6.13	1.42, 8.27	-1.26, 4.66	1.94, 6.46	
Difference (95% CI) in CFB [2]		3.75 (-1.85, 9.35)		2.50 (-0.70, 5.70)	
p-value [3]		0.184		0.125	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	42.26 (12.946)	45.68 (9.487)	43.30 (10.298)	43.29 (12.494)	
Median	39.59	45.68	45.68	45.68	
Min, Max	15.3, 63.9	15.3, 57.8	21.3, 63.9	15.3, 63.9	
C7D1 CFB					
n	15	34	44	87	
LS Mean (StdErr) [2]	-1.32 (2.565)	5.89 (1.788)	2.35 (1.816)	3.68 (1.388)	
95% CI [2]	-6.49, 3.84	2.29, 9.49	-1.25, 5.94	0.93, 6.42	
Difference (95% CI) in CFB [2]		7.21 (1.46, 12.96)		1.33 (-2.46, 5.11)	
Hedges'G (95% CI) in CFB		0.69 (0.08, 1.36)		0.10 (-0.26, 0.47)	
p-value [3]		0.015		0.488	
					0.108

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	51	97	
Mean (StdDev)	32.94 (10.046)	37.45 (10.035)	34.43 (10.971)	32.45 (10.791)	
Median	31.46	37.75	33.69	32.85	
Min, Max	15.8, 51.4	19.3, 52.1	13.8, 60.4	10.5, 61.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	35.37 (8.801)	40.83 (11.351)	36.94 (11.557)	36.49 (12.196)	
Median	36.13	45.64	35.38	36.36	
Min, Max	17.6, 47.9	18.5, 58.1	16.5, 61.2	13.0, 58.5	
C2D1 CFB					
n	15	36	50	95	
LS Mean (StdErr) [2]	1.65 (1.551)	2.56 (1.043)	0.68 (1.156)	2.24 (0.929)	
95% CI [2]	-1.47, 4.77	0.46, 4.66	-1.61, 2.96	0.40, 4.07	
Difference (95% CI) in CFB [2]		0.90 (-2.57, 4.37)		1.56 (-0.89, 4.01)	
p-value [3]		0.603		0.211	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	94	
Mean (StdDev)	34.71 (8.323)	41.43 (11.741)	36.67 (10.802)	37.81 (12.202)	
Median	33.29	43.19	37.51	39.22	
Min, Max	17.4, 52.2	15.3, 58.0	15.1, 62.6	13.3, 61.4	
C3D1 CFB					
n	16	33	47	91	
LS Mean (StdErr) [2]	1.47 (1.609)	3.69 (1.155)	1.09 (1.156)	4.19 (0.895)	
95% CI [2]	-1.77, 4.71	1.36, 6.02	-1.19, 3.38	2.42, 5.96	
Difference (95% CI) in CFB [2]		2.22 (-1.42, 5.86)		3.10 (0.65, 5.55)	
p-value [3]		0.226		0.014	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	90	
Mean (StdDev)	34.64 (6.018)	41.48 (10.816)	37.31 (11.719)	38.01 (11.849)	
Median	36.16	42.30	37.50	39.93	
Min, Max	21.4, 47.0	22.5, 59.8	10.8, 61.5	12.8, 59.1	
C4D1 CFB					
n	14	34	42	87	
LS Mean (StdErr) [2]	3.96 (1.646)	4.72 (1.154)	0.76 (1.399)	3.46 (1.098)	
95% CI [2]	0.65, 7.28	2.39, 7.04	-2.01, 3.53	1.28, 5.63	
Difference (95% CI) in CFB [2]		0.75 (-2.93, 4.43)		2.69 (-0.19, 5.58)	
p-value [3]		0.682		0.067	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	89	
Mean (StdDev)	36.42 (9.872)	42.11 (10.951)	36.72 (11.711)	37.60 (12.379)	
Median	36.03	42.67	39.20	38.62	
Min, Max	20.5, 51.4	18.5, 57.1	13.5, 60.1	13.0, 64.3	
C5D1 CFB					
n	16	32	45	86	
LS Mean (StdErr) [2]	3.60 (1.615)	4.40 (1.197)	0.94 (1.344)	4.42 (1.045)	
95% CI [2]	0.35, 6.86	1.98, 6.81	-1.72, 3.60	2.35, 6.49	
Difference (95% CI) in CFB [2]		0.79 (-2.84, 4.42)		3.47 (0.61, 6.34)	
p-value [3]		0.662		0.018	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	46	91	
Mean (StdDev)	32.91 (8.137)	42.37 (10.941)	36.60 (11.837)	39.64 (12.221)	
Median	32.98	45.16	37.70	41.04	
Min, Max	19.6, 51.9	21.8, 61.0	16.4, 58.8	17.3, 59.1	
C6D1 CFB					
n	14	34	44	88	
LS Mean (StdErr) [2]	1.29 (2.052)	4.34 (1.397)	0.36 (1.315)	5.81 (1.014)	
95% CI [2]	-2.84, 5.43	1.53, 7.16	-2.24, 2.96	3.81, 7.82	
Difference (95% CI) in CFB [2]		3.05 (-1.55, 7.66)		5.45 (2.64, 8.26)	
p-value [3]		0.189		<0.001	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	35.38 (9.241)	41.14 (11.277)	38.26 (11.489)	39.33 (12.662)	
Median	35.76	39.94	37.41	39.60	
Min, Max	19.0, 51.2	15.4, 63.1	14.5, 63.2	12.5, 61.7	
C7D1 CFB					
n	15	34	44	86	
LS Mean (StdErr) [2]	2.76 (2.338)	3.35 (1.630)	1.10 (1.347)	4.45 (1.043)	
95% CI [2]	-1.95, 7.47	0.07, 6.63	-1.57, 3.76	2.38, 6.51	
Difference (95% CI) in CFB [2]		0.59 (-4.65, 5.83)		3.35 (0.54, 6.15)	
Hedges'G (95% CI) in CFB		0.06 (-0.56, 0.69)		0.35 (-0.01, 0.73)	
p-value [3]		0.821		0.020	
					0.358

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
Baseline					
n	16	37	51	97	
Mean (StdDev)	41.66 (11.513)	41.96 (10.779)	40.78 (10.496)	40.08 (10.417)	
Median	39.69	42.34	39.58	39.52	
Min, Max	23.1, 63.9	23.4, 64.0	19.2, 58.7	13.2, 61.0	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C2D1					
n	16	39	53	98	
Mean (StdDev)	43.28 (11.445)	42.13 (11.410)	42.36 (10.853)	42.71 (10.014)	
Median	42.95	42.27	42.37	43.25	
Min, Max	20.8, 61.7	20.8, 62.2	19.9, 64.4	19.0, 64.8	
C2D1 CFB					
n	15	36	50	95	
LS Mean (StdErr) [2]	1.14 (2.076)	0.48 (1.396)	2.65 (1.267)	4.05 (1.018)	
95% CI [2]	-3.03, 5.32	-2.33, 3.29	0.15, 5.16	2.04, 6.07	
Difference (95% CI) in CFB [2]		-0.66 (-5.30, 3.99)		1.40 (-1.28, 4.09)	
p-value [3]		0.776		0.304	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C3D1					
n	17	34	50	94	
Mean (StdDev)	44.62 (12.709)	45.61 (10.268)	43.52 (10.240)	42.53 (10.607)	
Median	43.25	48.45	44.32	44.86	
Min, Max	11.2, 60.6	25.8, 66.0	22.9, 63.3	13.8, 60.6	
C3D1 CFB					
n	16	33	47	91	
LS Mean (StdErr) [2]	2.08 (2.360)	3.80 (1.694)	3.44 (1.288)	3.53 (0.997)	
95% CI [2]	-2.67, 6.84	0.38, 7.21	0.90, 5.99	1.56, 5.50	
Difference (95% CI) in CFB [2]		1.71 (-3.63, 7.06)		0.09 (-2.64, 2.81)	
p-value [3]		0.521		0.951	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C4D1					
n	15	36	45	90	
Mean (StdDev)	44.62 (11.245)	44.61 (10.928)	41.58 (9.662)	44.17 (10.763)	
Median	42.33	45.36	41.05	45.37	
Min, Max	22.0, 59.4	23.4, 63.9	22.1, 59.7	13.7, 60.9	
C4D1 CFB					
n	14	34	42	87	
LS Mean (StdErr) [2]	0.37 (2.493)	2.50 (1.749)	3.15 (1.624)	5.26 (1.275)	
95% CI [2]	-4.65, 5.40	-1.03, 6.02	-0.06, 6.37	2.73, 7.78	
Difference (95% CI) in CFB [2]		2.13 (-3.45, 7.70)		2.11 (-1.24, 5.46)	
p-value [3]		0.446		0.216	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C5D1					
n	17	36	47	89	
Mean (StdDev)	44.43 (12.198)	45.90 (9.844)	42.68 (11.525)	44.12 (10.771)	
Median	43.54	46.95	45.32	45.02	
Min, Max	14.1, 59.4	27.4, 64.4	18.6, 61.6	19.5, 62.5	
C5D1 CFB					
n	16	32	45	86	
LS Mean (StdErr) [2]	1.22 (2.115)	2.82 (1.568)	2.49 (1.729)	4.82 (1.344)	
95% CI [2]	-3.04, 5.49	-0.34, 5.98	-0.93, 5.91	2.16, 7.48	
Difference (95% CI) in CFB [2]		1.59 (-3.16, 6.35)		2.33 (-1.35, 6.01)	
p-value [3]		0.503		0.213	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C6D1					
n	15	38	46	91	
Mean (StdDev)	46.15 (9.501)	44.56 (10.199)	42.45 (10.811)	43.57 (11.176)	
Median	43.94	45.60	41.52	45.44	
Min, Max	34.4, 60.1	23.5, 61.4	24.1, 61.4	12.1, 61.5	
C6D1 CFB					
n	14	34	44	88	
LS Mean (StdErr) [2]	2.95 (2.469)	3.57 (1.680)	1.98 (1.654)	3.60 (1.276)	
95% CI [2]	-2.03, 7.92	0.18, 6.95	-1.29, 5.25	1.08, 6.13	
Difference (95% CI) in CFB [2]		0.62 (-4.92, 6.16)		1.62 (-1.91, 5.16)	
p-value [3]		0.822		0.365	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.2a
Change from Baseline of SF-12 by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Sex = Male		Sex = Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	Test of Interaction p-value [1]
C7D1					
n	16	38	46	89	
Mean (StdDev)	44.30 (13.148)	45.86 (9.036)	42.73 (10.972)	43.56 (12.171)	
Median	44.79	46.65	43.12	43.65	
Min, Max	12.1, 60.9	21.1, 63.3	21.3, 64.9	12.0, 62.7	
C7D1 CFB					
n	15	34	44	86	
LS Mean (StdErr) [2]	0.83 (2.230)	4.33 (1.554)	1.95 (1.726)	3.80 (1.337)	
95% CI [2]	-3.66, 5.33	1.20, 7.46	-1.47, 5.37	1.15, 6.45	
Difference (95% CI) in CFB [2]		3.50 (-1.50, 8.49)		1.85 (-1.75, 5.44)	
Hedges'G (95% CI) in CFB		0.38 (-0.23, 1.03)		0.15 (-0.21, 0.52)	
p-value [3]		0.166		0.311	
					0.660

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-sex-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	37	80	
Mean (StdDev)	40.25 (13.246)	38.46 (12.163)	36.27 (10.945)	36.74 (11.048)	
Median	39.69	39.69	31.27	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	41.59 (12.234)	43.11 (12.013)	39.24 (10.155)	38.82 (11.712)	
Median	39.69	48.10	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C2D1 CFB					
n	28	54	37	78	
LS Mean (StdErr) [2]	0.73 (1.792)	4.34 (1.401)	2.25 (1.152)	1.10 (0.853)	
95% CI [2]	-2.84, 4.30	1.55, 7.13	-0.03, 4.54	-0.59, 2.79	
Difference (95% CI) in CFB [2]		3.61 (-0.30, 7.52)		-1.15 (-3.64, 1.33)	
p-value [3]		0.070		0.360	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	52	37	76	
Mean (StdDev)	40.25 (10.810)	43.08 (12.274)	39.23 (10.295)	39.69 (11.820)	
Median	39.69	39.69	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C3D1 CFB					
n	27	49	36	76	
LS Mean (StdErr) [2]	1.03 (1.858)	5.64 (1.468)	2.24 (1.278)	2.29 (0.925)	
95% CI [2]	-2.68, 4.73	2.72, 8.57	-0.29, 4.77	0.46, 4.12	
Difference (95% CI) in CFB [2]		4.62 (0.54, 8.69)		0.05 (-2.71, 2.82)	
p-value [3]		0.027		0.970	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	40.78 (11.981)	44.22 (11.110)	39.23 (10.295)	39.58 (11.701)	
Median	39.69	48.10	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C4D1 CFB					
n	20	49	36	76	
LS Mean (StdErr) [2]	4.30 (1.966)	8.42 (1.464)	2.46 (1.538)	2.58 (1.122)	
95% CI [2]	0.37, 8.23	5.49, 11.34	-0.59, 5.51	0.36, 4.81	
Difference (95% CI) in CFB [2]		4.11 (0.05, 8.18)		0.12 (-3.20, 3.45)	
p-value [3]		0.047		0.941	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	37	78	
Mean (StdDev)	41.24 (13.001)	43.80 (10.939)	39.69 (11.564)	40.44 (12.143)	
Median	39.69	39.69	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C5D1 CFB					
n	25	42	36	77	
LS Mean (StdErr) [2]	2.21 (1.937)	7.56 (1.584)	2.19 (1.504)	2.76 (1.092)	
95% CI [2]	-1.66, 6.08	4.39, 10.73	-0.79, 5.17	0.60, 4.92	
Difference (95% CI) in CFB [2]		5.35 (1.12, 9.59)		0.57 (-2.68, 3.82)	
p-value [3]		0.014		0.729	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	40.69 (11.978)	45.19 (11.038)	38.32 (10.955)	40.78 (12.684)	
Median	39.69	48.10	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C6D1 CFB					
n	23	47	36	76	
LS Mean (StdErr) [2]	0.48 (1.884)	7.36 (1.443)	1.25 (1.536)	3.25 (1.112)	
95% CI [2]	-3.28, 4.24	4.48, 10.24	-1.79, 4.30	1.04, 5.45	
Difference (95% CI) in CFB [2]		6.87 (2.76, 10.98)		1.99 (-1.33, 5.32)	
p-value [3]		0.001		0.237	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	42.04 (12.971)	45.58 (10.785)	38.55 (9.948)	39.90 (12.802)	
Median	48.10	48.10	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C7D1 CFB					
n	23	45	36	76	
LS Mean (StdErr) [2]	-0.07 (2.063)	6.64 (1.613)	1.41 (1.779)	2.32 (1.287)	
95% CI [2]	-4.19, 4.06	3.41, 9.86	-2.11, 4.94	-0.23, 4.87	
Difference (95% CI) in CFB [2]		6.70 (2.42, 10.99)		0.91 (-2.94, 4.75)	
Hedges'G (95% CI) in CFB		0.63 (0.13, 1.17)		0.08 (-0.32, 0.48)	
p-value [3]		0.003		0.641	
					0.047

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	37	80	
Mean (StdDev)	35.86 (8.349)	36.31 (8.751)	33.54 (7.187)	33.73 (8.505)	
Median	34.51	39.00	30.03	34.51	
Min, Max	21.0, 48.0	21.0, 57.0	21.0, 52.5	21.0, 57.0	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	38.86 (10.334)	39.46 (10.028)	34.40 (8.050)	36.24 (10.005)	
Median	39.00	39.00	34.51	34.51	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 52.5	21.0, 57.0	
C2D1 CFB					
n	28	54	37	78	
LS Mean (StdErr) [2]	1.44 (1.600)	1.42 (1.251)	0.36 (1.184)	2.13 (0.877)	
95% CI [2]	-1.75, 4.62	-1.07, 3.91	-1.99, 2.70	0.39, 3.87	
Difference (95% CI) in CFB [2]		-0.02 (-3.51, 3.47)		1.78 (-0.78, 4.33)	
p-value [3]		0.991		0.171	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	52	37	76	
Mean (StdDev)	39.45 (9.603)	40.47 (10.471)	34.64 (9.315)	38.35 (10.071)	
Median	39.00	39.00	34.51	39.00	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 52.5	21.0, 57.0	
C3D1 CFB					
n	27	49	36	76	
LS Mean (StdErr) [2]	2.89 (1.760)	3.69 (1.391)	0.64 (1.337)	4.31 (0.967)	
95% CI [2]	-0.62, 6.40	0.91, 6.46	-2.01, 3.29	2.39, 6.22	
Difference (95% CI) in CFB [2]		0.79 (-3.07, 4.66)		3.67 (0.78, 6.56)	
p-value [3]		0.683		0.013	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	51	37	76	
Mean (StdDev)	39.39 (10.564)	42.35 (9.952)	35.36 (9.514)	38.30 (10.212)	
Median	39.00	43.49	39.00	39.00	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 52.5	21.0, 57.0	
C4D1 CFB					
n	20	48	36	75	
LS Mean (StdErr) [2]	3.91 (2.117)	5.11 (1.579)	1.52 (1.329)	4.47 (0.982)	
95% CI [2]	-0.32, 8.14	1.96, 8.27	-1.11, 4.16	2.53, 6.42	
Difference (95% CI) in CFB [2]		1.20 (-3.18, 5.59)		2.95 (0.08, 5.83)	
p-value [3]		0.585		0.044	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	37	78	
Mean (StdDev)	38.67 (10.186)	41.77 (9.246)	36.09 (8.740)	38.31 (10.311)	
Median	39.00	39.00	39.00	39.00	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 57.0	21.0, 57.0	
C5D1 CFB					
n	25	42	36	77	
LS Mean (StdErr) [2]	2.79 (1.759)	5.65 (1.439)	1.93 (1.437)	4.25 (1.043)	
95% CI [2]	-0.73, 6.30	2.77, 8.52	-0.92, 4.78	2.18, 6.32	
Difference (95% CI) in CFB [2]		2.86 (-0.99, 6.71)		2.32 (-0.79, 5.42)	
p-value [3]		0.142		0.142	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	38.11 (10.204)	44.18 (8.637)	34.76 (9.579)	38.54 (10.643)	
Median	34.51	47.98	34.51	39.00	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 57.0	21.0, 57.0	
C6D1 CFB					
n	23	47	36	76	
LS Mean (StdErr) [2]	1.64 (1.896)	6.66 (1.452)	0.76 (1.527)	4.55 (1.105)	
95% CI [2]	-2.15, 5.42	3.76, 9.56	-2.27, 3.78	2.36, 6.73	
Difference (95% CI) in CFB [2]		5.02 (0.88, 9.16)		3.79 (0.49, 7.09)	
p-value [3]		0.018		0.025	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	41.16 (10.929)	44.21 (9.441)	35.85 (9.632)	38.13 (10.876)	
Median	43.49	45.74	34.51	39.00	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 57.0	21.0, 57.0	
C7D1 CFB					
n	23	45	36	76	
LS Mean (StdErr) [2]	3.91 (2.054)	6.84 (1.607)	1.66 (1.630)	3.65 (1.179)	
95% CI [2]	-0.19, 8.02	3.63, 10.05	-1.57, 4.89	1.31, 5.99	
Difference (95% CI) in CFB [2]		2.93 (-1.34, 7.19)		1.99 (-1.54, 5.51)	
Hedges'G (95% CI) in CFB		0.28 (-0.23, 0.80)		0.20 (-0.20, 0.60)	
p-value [3]		0.175		0.266	
					0.732

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	37	79	
Mean (StdDev)	34.90 (12.574)	34.59 (12.464)	30.44 (8.908)	30.55 (10.752)	
Median	36.27	36.27	26.00	26.00	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 46.5	15.7, 56.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	38.26 (11.983)	40.10 (11.895)	33.84 (10.527)	37.32 (12.990)	
Median	36.27	46.54	36.27	36.27	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C2D1 CFB					
n	28	54	37	77	
LS Mean (StdErr) [2]	1.27 (1.991)	4.33 (1.558)	2.10 (1.887)	5.27 (1.418)	
95% CI [2]	-2.69, 5.24	1.23, 7.43	-1.64, 5.84	2.46, 8.07	
Difference (95% CI) in CFB [2]		3.06 (-1.29, 7.40)		3.17 (-0.90, 7.24)	
p-value [3]		0.166		0.126	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	52	37	76	
Mean (StdDev)	40.72 (10.335)	41.60 (10.856)	33.49 (11.000)	38.30 (12.664)	
Median	36.27	46.54	36.27	36.27	
Min, Max	26.0, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C3D1 CFB					
n	27	49	36	75	
LS Mean (StdErr) [2]	6.52 (2.088)	9.03 (1.650)	2.30 (1.663)	6.75 (1.220)	
95% CI [2]	2.36, 10.68	5.74, 12.32	-1.00, 5.59	4.33, 9.17	
Difference (95% CI) in CFB [2]		2.51 (-2.07, 7.10)		4.46 (0.86, 8.06)	
p-value [3]		0.278		0.016	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	51	37	77	
Mean (StdDev)	40.73 (11.090)	40.90 (11.676)	33.49 (9.576)	38.00 (13.266)	
Median	36.27	46.54	36.27	36.27	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 46.5	15.7, 56.8	
C4D1 CFB					
n	20	48	36	75	
LS Mean (StdErr) [2]	4.96 (2.724)	6.21 (2.115)	1.77 (1.828)	6.14 (1.351)	
95% CI [2]	-0.49, 10.40	1.98, 10.43	-1.85, 5.39	3.46, 8.82	
Difference (95% CI) in CFB [2]		1.25 (-4.32, 6.81)		4.37 (0.42, 8.33)	
p-value [3]		0.655		0.031	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	37	78	
Mean (StdDev)	39.69 (12.416)	41.08 (12.823)	33.49 (11.263)	38.11 (13.111)	
Median	46.54	46.54	36.27	36.27	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C5D1 CFB					
n	25	42	36	76	
LS Mean (StdErr) [2]	2.85 (2.252)	5.78 (1.842)	2.09 (1.979)	6.61 (1.456)	
95% CI [2]	-1.65, 7.35	2.09, 9.46	-1.84, 6.01	3.72, 9.49	
Difference (95% CI) in CFB [2]		2.93 (-2.00, 7.85)		4.52 (0.25, 8.80)	
p-value [3]		0.239		0.038	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	36	77	
Mean (StdDev)	37.91 (12.814)	42.39 (11.188)	33.70 (12.609)	38.94 (13.779)	
Median	36.27	46.54	36.27	46.54	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C6D1 CFB					
n	23	47	35	75	
LS Mean (StdErr) [2]	2.59 (2.266)	7.99 (1.735)	1.45 (1.943)	6.71 (1.416)	
95% CI [2]	-1.94, 7.11	4.52, 11.45	-2.40, 5.31	3.90, 9.52	
Difference (95% CI) in CFB [2]		5.40 (0.45, 10.34)		5.26 (1.04, 9.47)	
p-value [3]		0.033		0.015	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	40.38 (11.859)	42.84 (12.056)	35.99 (10.957)	37.60 (13.974)	
Median	36.27	46.54	36.27	36.27	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C7D1 CFB					
n	23	45	36	75	
LS Mean (StdErr) [2]	1.72 (2.383)	5.91 (1.864)	3.08 (1.959)	4.34 (1.437)	
95% CI [2]	-3.04, 6.48	2.18, 9.63	-0.81, 6.96	1.49, 7.19	
Difference (95% CI) in CFB [2]		4.19 (-0.76, 9.14)		1.26 (-2.98, 5.51)	
Hedges'G (95% CI) in CFB		0.34 (-0.16, 0.87)		0.10 (-0.30, 0.51)	
p-value [3]		0.096		0.556	
					0.371

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	37	80	
Mean (StdDev)	36.14 (11.404)	35.96 (10.446)	31.94 (9.244)	32.36 (8.797)	
Median	30.05	30.05	30.05	30.05	
Min, Max	19.4, 61.9	19.4, 55.5	19.4, 55.5	19.4, 55.5	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	38.61 (11.315)	38.33 (10.562)	34.24 (10.225)	33.89 (10.476)	
Median	30.05	44.92	30.05	30.05	
Min, Max	19.4, 55.5	19.4, 55.5	19.4, 55.5	19.4, 55.5	
C2D1 CFB					
n	28	54	37	78	
LS Mean (StdErr) [2]	1.05 (1.768)	2.29 (1.383)	2.35 (1.522)	1.59 (1.127)	
95% CI [2]	-2.47, 4.57	-0.46, 5.05	-0.67, 5.36	-0.65, 3.82	
Difference (95% CI) in CFB [2]		1.24 (-2.62, 5.10)		-0.76 (-4.04, 2.52)	
p-value [3]		0.524		0.648	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	52	37	76	
Mean (StdDev)	36.35 (10.128)	39.16 (11.308)	34.24 (9.933)	36.22 (10.762)	
Median	30.05	44.92	30.05	30.05	
Min, Max	19.4, 55.5	19.4, 55.5	19.4, 55.5	19.4, 61.9	
C3D1 CFB					
n	27	49	36	76	
LS Mean (StdErr) [2]	-1.35 (1.993)	3.62 (1.574)	1.62 (1.615)	3.27 (1.169)	
95% CI [2]	-5.32, 2.63	0.48, 6.76	-1.58, 4.82	0.96, 5.59	
Difference (95% CI) in CFB [2]		4.97 (0.60, 9.34)		1.65 (-1.84, 5.15)	
p-value [3]		0.027		0.350	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	39.01 (11.898)	40.71 (9.943)	34.12 (9.506)	35.37 (11.240)	
Median	44.92	44.92	30.05	30.05	
Min, Max	19.4, 61.9	19.4, 55.5	19.4, 55.5	19.4, 55.5	
C4D1 CFB					
n	20	49	36	76	
LS Mean (StdErr) [2]	-0.35 (2.258)	3.12 (1.682)	1.95 (1.744)	2.72 (1.273)	
95% CI [2]	-4.86, 4.16	-0.24, 6.48	-1.51, 5.41	0.19, 5.24	
Difference (95% CI) in CFB [2]		3.47 (-1.19, 8.14)		0.77 (-3.01, 4.54)	
p-value [3]		0.142		0.688	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	37	78	
Mean (StdDev)	38.23 (11.391)	40.67 (10.530)	34.93 (8.956)	36.42 (10.708)	
Median	30.05	44.92	30.05	30.05	
Min, Max	19.4, 61.9	19.4, 55.5	19.4, 44.9	19.4, 55.5	
C5D1 CFB					
n	25	42	36	77	
LS Mean (StdErr) [2]	1.39 (2.053)	4.50 (1.680)	2.52 (1.782)	3.51 (1.294)	
95% CI [2]	-2.72, 5.49	1.14, 7.85	-1.02, 6.05	0.95, 6.08	
Difference (95% CI) in CFB [2]		3.11 (-1.38, 7.60)		0.99 (-2.85, 4.84)	
p-value [3]		0.172		0.609	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	38.63 (12.561)	43.04 (9.128)	34.64 (10.059)	35.84 (11.319)	
Median	44.92	44.92	30.05	30.05	
Min, Max	19.4, 61.9	19.4, 55.5	19.4, 55.5	19.4, 55.5	
C6D1 CFB					
n	23	47	36	76	
LS Mean (StdErr) [2]	0.76 (1.912)	6.80 (1.464)	2.33 (1.777)	3.22 (1.286)	
95% CI [2]	-3.06, 4.58	3.88, 9.73	-1.20, 5.85	0.68, 5.77	
Difference (95% CI) in CFB [2]		6.04 (1.87, 10.22)		0.90 (-2.95, 4.74)	
p-value [3]		0.005		0.645	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	39.82 (11.924)	43.64 (8.542)	34.52 (9.643)	36.01 (11.342)	
Median	44.92	44.92	30.05	30.05	
Min, Max	19.4, 55.5	19.4, 55.5	19.4, 55.5	19.4, 55.5	
C7D1 CFB					
n	23	45	36	76	
LS Mean (StdErr) [2]	-0.66 (2.200)	6.30 (1.721)	2.20 (1.755)	3.00 (1.270)	
95% CI [2]	-5.06, 3.74	2.86, 9.74	-1.28, 5.67	0.48, 5.52	
Difference (95% CI) in CFB [2]		6.96 (2.39, 11.53)		0.80 (-2.99, 4.60)	
Hedges'G (95% CI) in CFB		0.61 (0.11, 1.16)		0.07 (-0.33, 0.48)	
p-value [3]		0.003		0.676	
					0.055

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	37	80	
Mean (StdDev)	38.57 (9.406)	37.36 (8.024)	40.09 (8.552)	37.76 (8.627)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 57.8	28.5, 57.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	41.08 (8.426)	41.06 (9.762)	40.56 (9.469)	39.12 (9.325)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 67.5	28.5, 57.8	
C2D1 CFB					
n	28	54	37	78	
LS Mean (StdErr) [2]	2.10 (1.818)	4.52 (1.422)	0.60 (1.341)	1.40 (0.993)	
95% CI [2]	-1.52, 5.72	1.69, 7.35	-2.06, 3.26	-0.57, 3.37	
Difference (95% CI) in CFB [2]		2.42 (-1.55, 6.39)		0.80 (-2.09, 3.69)	
p-value [3]		0.229		0.585	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	52	37	76	
Mean (StdDev)	40.20 (9.720)	41.06 (10.099)	42.73 (9.365)	40.69 (9.705)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 67.5	28.5, 57.8	
C3D1 CFB					
n	27	49	36	76	
LS Mean (StdErr) [2]	1.28 (1.923)	4.45 (1.519)	3.08 (1.353)	2.61 (0.979)	
95% CI [2]	-2.56, 5.11	1.42, 7.48	0.39, 5.76	0.67, 4.55	
Difference (95% CI) in CFB [2]		3.18 (-1.05, 7.40)		-0.46 (-3.39, 2.46)	
p-value [3]		0.138		0.754	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	38.25 (8.318)	41.44 (9.408)	41.41 (8.619)	40.91 (10.806)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 48.0	28.5, 57.8	28.5, 57.8	28.5, 57.8	
C4D1 CFB					
n	20	49	36	76	
LS Mean (StdErr) [2]	1.11 (2.063)	3.54 (1.536)	1.18 (1.782)	2.64 (1.301)	
95% CI [2]	-3.01, 5.23	0.47, 6.61	-2.35, 4.72	0.06, 5.22	
Difference (95% CI) in CFB [2]		2.43 (-1.83, 6.69)		1.46 (-2.40, 5.31)	
p-value [3]		0.259		0.455	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	37	78	
Mean (StdDev)	41.14 (8.896)	42.81 (9.287)	40.36 (9.790)	40.75 (10.360)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 57.8	28.5, 67.5	
C5D1 CFB					
n	25	42	36	77	
LS Mean (StdErr) [2]	3.79 (2.012)	6.30 (1.646)	0.34 (1.747)	2.70 (1.268)	
95% CI [2]	-0.24, 7.81	3.01, 9.59	-3.12, 3.80	0.19, 5.22	
Difference (95% CI) in CFB [2]		2.52 (-1.88, 6.92)		2.36 (-1.41, 6.14)	
p-value [3]		0.257		0.217	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	39.03 (8.868)	43.31 (10.127)	39.57 (9.243)	42.18 (9.914)	
Median	38.25	43.13	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 57.8	28.5, 67.5	
C6D1 CFB					
n	23	47	36	76	
LS Mean (StdErr) [2]	0.88 (1.886)	5.52 (1.444)	0.18 (1.638)	4.23 (1.185)	
95% CI [2]	-2.88, 4.65	2.63, 8.40	-3.07, 3.42	1.88, 6.58	
Difference (95% CI) in CFB [2]		4.64 (0.52, 8.75)		4.05 (0.51, 7.60)	
p-value [3]		0.028		0.025	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	40.98 (10.353)	43.32 (10.472)	41.94 (10.623)	41.29 (10.286)	
Median	38.25	48.00	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 67.5	28.5, 67.5	
C7D1 CFB					
n	23	45	36	76	
LS Mean (StdErr) [2]	3.97 (2.195)	6.51 (1.717)	2.00 (1.623)	3.02 (1.175)	
95% CI [2]	-0.42, 8.36	3.08, 9.94	-1.22, 5.22	0.69, 5.35	
Difference (95% CI) in CFB [2]		2.54 (-2.02, 7.10)		1.02 (-2.49, 4.53)	
Hedges'G (95% CI) in CFB		0.22 (-0.28, 0.74)		0.10 (-0.30, 0.50)	
p-value [3]		0.270		0.566	
					0.595

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	37	80	
Mean (StdDev)	38.93 (12.468)	38.45 (11.399)	35.48 (11.054)	37.15 (11.064)	
Median	36.29	36.29	36.29	36.29	
Min, Max	16.5, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	42.36 (10.454)	42.34 (11.500)	37.85 (10.940)	39.84 (11.182)	
Median	46.20	46.20	36.29	36.29	
Min, Max	16.5, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C2D1 CFB					
n	28	54	37	78	
LS Mean (StdErr) [2]	1.81 (2.064)	3.55 (1.614)	2.06 (1.870)	2.24 (1.386)	
95% CI [2]	-2.30, 5.92	0.33, 6.76	-1.64, 5.77	-0.51, 4.99	
Difference (95% CI) in CFB [2]		1.74 (-2.77, 6.24)		0.18 (-3.86, 4.21)	
p-value [3]		0.445		0.931	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	52	37	76	
Mean (StdDev)	42.56 (11.492)	42.58 (11.453)	39.50 (10.974)	39.68 (11.848)	
Median	46.20	46.20	36.29	36.29	
Min, Max	16.5, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C3D1 CFB					
n	27	49	36	76	
LS Mean (StdErr) [2]	4.18 (1.997)	4.80 (1.578)	3.73 (1.775)	2.19 (1.284)	
95% CI [2]	0.19, 8.16	1.66, 7.95	0.21, 7.24	-0.35, 4.74	
Difference (95% CI) in CFB [2]		0.63 (-3.76, 5.01)		-1.53 (-5.37, 2.31)	
p-value [3]		0.776		0.430	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	41.46 (11.908)	42.58 (10.578)	38.43 (10.486)	40.66 (13.213)	
Median	46.20	46.20	36.29	46.20	
Min, Max	16.5, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C4D1 CFB					
n	20	49	36	76	
LS Mean (StdErr) [2]	0.94 (2.488)	3.84 (1.853)	2.78 (1.979)	3.42 (1.444)	
95% CI [2]	-4.03, 5.91	0.13, 7.54	-1.14, 6.70	0.55, 6.28	
Difference (95% CI) in CFB [2]		2.89 (-2.25, 8.03)		0.63 (-3.65, 4.92)	
p-value [3]		0.265		0.770	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	37	78	
Mean (StdDev)	43.63 (12.171)	44.72 (11.506)	36.82 (10.947)	42.13 (12.109)	
Median	46.20	46.20	36.29	46.20	
Min, Max	16.5, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C5D1 CFB					
n	25	42	36	77	
LS Mean (StdErr) [2]	5.07 (2.392)	8.19 (1.956)	0.13 (2.033)	3.91 (1.476)	
95% CI [2]	0.29, 9.85	4.28, 12.10	-3.90, 4.16	0.99, 6.84	
Difference (95% CI) in CFB [2]		3.12 (-2.11, 8.35)		3.78 (-0.61, 8.17)	
p-value [3]		0.238		0.091	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	41.04 (12.183)	45.82 (10.003)	37.89 (11.088)	40.53 (12.809)	
Median	46.20	46.20	36.29	46.20	
Min, Max	16.5, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C6D1 CFB					
n	23	47	36	76	
LS Mean (StdErr) [2]	0.41 (2.503)	6.96 (1.917)	2.38 (2.016)	3.01 (1.459)	
95% CI [2]	-4.59, 5.41	3.13, 10.79	-1.61, 6.38	0.12, 5.90	
Difference (95% CI) in CFB [2]		6.54 (1.08, 12.01)		0.62 (-3.74, 4.99)	
p-value [3]		0.020		0.777	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	45.01 (10.830)	45.01 (11.617)	37.63 (11.722)	41.31 (12.522)	
Median	46.20	46.20	36.29	46.20	
Min, Max	26.4, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C7D1 CFB					
n	23	45	36	76	
LS Mean (StdErr) [2]	1.94 (2.537)	6.03 (1.985)	1.99 (2.131)	3.52 (1.542)	
95% CI [2]	-3.13, 7.01	2.06, 9.99	-2.24, 6.21	0.47, 6.58	
Difference (95% CI) in CFB [2]		4.09 (-1.18, 9.36)		1.54 (-3.07, 6.15)	
Hedges'G (95% CI) in CFB		0.31 (-0.19, 0.84)		0.12 (-0.28, 0.52)	
p-value [3]		0.126		0.510	
					0.488

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	37	80	
Mean (StdDev)	41.85 (11.295)	38.27 (10.732)	33.90 (11.377)	38.17 (12.524)	
Median	39.27	39.27	33.75	36.51	
Min, Max	22.7, 55.8	17.2, 55.8	11.7, 55.8	11.7, 55.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	43.90 (11.047)	43.01 (10.012)	37.09 (10.700)	40.54 (12.733)	
Median	44.79	44.79	39.27	42.03	
Min, Max	22.7, 55.8	17.2, 55.8	17.2, 55.8	11.7, 55.8	
C2D1 CFB					
n	28	54	37	78	
LS Mean (StdErr) [2]	3.08 (1.869)	5.59 (1.462)	3.41 (1.707)	2.84 (1.265)	
95% CI [2]	-0.64, 6.80	2.68, 8.50	0.03, 6.79	0.33, 5.34	
Difference (95% CI) in CFB [2]		2.51 (-1.57, 6.59)		-0.57 (-4.25, 3.11)	
p-value [3]		0.225		0.759	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	52	37	76	
Mean (StdDev)	46.45 (11.426)	41.61 (12.620)	36.74 (11.532)	42.10 (11.382)	
Median	50.31	44.79	33.75	44.79	
Min, Max	11.7, 55.8	11.7, 55.8	11.7, 55.8	11.7, 55.8	
C3D1 CFB					
n	27	49	36	76	
LS Mean (StdErr) [2]	5.09 (2.260)	5.03 (1.786)	3.02 (1.669)	4.33 (1.207)	
95% CI [2]	0.58, 9.60	1.47, 8.59	-0.29, 6.32	1.94, 6.72	
Difference (95% CI) in CFB [2]		-0.05 (-5.02, 4.91)		1.31 (-2.30, 4.92)	
p-value [3]		0.982		0.472	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	51	37	77	
Mean (StdDev)	45.27 (10.773)	43.92 (10.666)	35.99 (11.449)	41.85 (12.585)	
Median	44.79	44.79	33.75	44.79	
Min, Max	22.7, 55.8	17.2, 55.8	17.2, 55.8	11.7, 55.8	
C4D1 CFB					
n	20	48	36	76	
LS Mean (StdErr) [2]	4.77 (2.705)	6.15 (2.017)	2.27 (1.911)	4.33 (1.395)	
95% CI [2]	-0.64, 10.17	2.12, 10.18	-1.51, 6.06	1.57, 7.10	
Difference (95% CI) in CFB [2]		1.38 (-4.22, 6.99)		2.06 (-2.07, 6.20)	
p-value [3]		0.624		0.325	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	37	78	
Mean (StdDev)	46.22 (11.206)	44.56 (9.963)	37.33 (11.505)	42.31 (11.721)	
Median	50.31	44.79	33.75	44.79	
Min, Max	17.2, 55.8	22.7, 55.8	11.7, 55.8	11.7, 55.8	
C5D1 CFB					
n	25	42	36	77	
LS Mean (StdErr) [2]	3.59 (2.318)	5.67 (1.896)	3.18 (2.058)	4.47 (1.494)	
95% CI [2]	-1.05, 8.22	1.88, 9.46	-0.90, 7.26	1.51, 7.43	
Difference (95% CI) in CFB [2]		2.08 (-2.99, 7.15)		1.29 (-3.15, 5.73)	
p-value [3]		0.415		0.566	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	37	77	
Mean (StdDev)	47.88 (10.457)	45.75 (9.573)	36.59 (12.383)	40.27 (12.589)	
Median	55.83	47.55	33.75	44.79	
Min, Max	22.7, 55.8	22.7, 55.8	11.7, 55.8	11.7, 55.8	
C6D1 CFB					
n	23	47	36	76	
LS Mean (StdErr) [2]	5.12 (2.547)	6.95 (1.951)	2.14 (2.140)	2.33 (1.548)	
95% CI [2]	0.03, 10.21	3.05, 10.84	-2.10, 6.38	-0.74, 5.40	
Difference (95% CI) in CFB [2]		1.82 (-3.73, 7.38)		0.19 (-4.44, 4.82)	
p-value [3]		0.514		0.934	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	46.34 (10.141)	44.24 (9.672)	36.44 (12.853)	41.64 (12.643)	
Median	50.31	44.79	33.75	44.79	
Min, Max	28.2, 55.8	17.2, 55.8	11.7, 55.8	11.7, 55.8	
C7D1 CFB					
n	23	45	36	76	
LS Mean (StdErr) [2]	-0.27 (2.001)	4.66 (1.565)	1.66 (2.000)	2.98 (1.447)	
95% CI [2]	-4.27, 3.73	1.53, 7.79	-2.30, 5.63	0.12, 5.85	
Difference (95% CI) in CFB [2]		4.93 (0.77, 9.09)		1.32 (-3.00, 5.65)	
Hedges'G (95% CI) in CFB		0.48 (-0.03, 1.01)		0.11 (-0.29, 0.51)	
p-value [3]		0.021		0.545	
					0.252

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	37	80	
Mean (StdDev)	44.26 (9.543)	38.60 (10.456)	39.10 (9.334)	40.66 (9.955)	
Median	45.68	39.59	39.59	39.59	
Min, Max	27.4, 57.8	15.3, 63.9	21.3, 63.9	21.3, 63.9	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	43.52 (10.600)	40.93 (11.243)	41.20 (10.362)	42.32 (9.836)	
Median	45.68	39.59	39.59	39.59	
Min, Max	21.3, 57.8	15.3, 63.9	27.4, 63.9	15.3, 57.8	
C2D1 CFB					
n	28	54	37	78	
LS Mean (StdErr) [2]	0.07 (1.456)	3.63 (1.139)	1.90 (1.298)	1.70 (0.962)	
95% CI [2]	-2.83, 2.97	1.36, 5.90	-0.68, 4.47	-0.21, 3.60	
Difference (95% CI) in CFB [2]		3.55 (0.38, 6.73)		-0.20 (-3.00, 2.60)	
p-value [3]		0.029		0.888	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	52	37	76	
Mean (StdDev)	46.29 (9.226)	42.05 (11.571)	40.25 (10.515)	44.64 (10.578)	
Median	45.68	45.68	39.59	45.68	
Min, Max	27.4, 57.8	21.3, 57.8	15.3, 63.9	15.3, 63.9	
C3D1 CFB					
n	27	49	36	76	
LS Mean (StdErr) [2]	1.79 (1.619)	4.61 (1.279)	1.12 (1.636)	3.90 (1.184)	
95% CI [2]	-1.44, 5.01	2.06, 7.16	-2.12, 4.37	1.55, 6.25	
Difference (95% CI) in CFB [2]		2.83 (-0.73, 6.38)		2.78 (-0.76, 6.31)	
p-value [3]		0.117		0.123	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	52	37	77	
Mean (StdDev)	45.41 (9.074)	45.21 (10.697)	41.07 (10.078)	43.70 (11.008)	
Median	45.68	45.68	39.59	45.68	
Min, Max	27.4, 57.8	21.3, 63.9	21.3, 63.9	15.3, 63.9	
C4D1 CFB					
n	20	49	36	76	
LS Mean (StdErr) [2]	2.76 (2.167)	8.17 (1.614)	2.56 (1.572)	3.90 (1.147)	
95% CI [2]	-1.57, 7.09	4.95, 11.40	-0.56, 5.67	1.63, 6.17	
Difference (95% CI) in CFB [2]		5.41 (0.93, 9.89)		1.34 (-2.06, 4.74)	
p-value [3]		0.019		0.436	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	37	78	
Mean (StdDev)	47.25 (9.779)	43.87 (10.298)	39.92 (10.820)	43.88 (10.473)	
Median	45.68	45.68	39.59	45.68	
Min, Max	27.4, 63.9	15.3, 63.9	21.3, 63.9	21.3, 63.9	
C5D1 CFB					
n	25	42	36	77	
LS Mean (StdErr) [2]	2.44 (1.879)	4.79 (1.537)	0.92 (1.732)	3.78 (1.257)	
95% CI [2]	-1.31, 6.20	1.72, 7.86	-2.51, 4.35	1.29, 6.27	
Difference (95% CI) in CFB [2]		2.35 (-1.76, 6.46)		2.86 (-0.87, 6.60)	
p-value [3]		0.257		0.132	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	36	77	
Mean (StdDev)	45.92 (10.751)	44.62 (10.131)	41.12 (9.008)	42.83 (11.103)	
Median	45.68	45.68	39.59	45.68	
Min, Max	27.4, 63.9	15.3, 63.9	27.4, 63.9	15.3, 63.9	
C6D1 CFB					
n	23	47	35	76	
LS Mean (StdErr) [2]	0.63 (1.766)	6.31 (1.353)	2.16 (1.738)	3.11 (1.250)	
95% CI [2]	-2.89, 4.16	3.61, 9.01	-1.28, 5.61	0.63, 5.59	
Difference (95% CI) in CFB [2]		5.68 (1.83, 9.53)		0.95 (-2.82, 4.71)	
p-value [3]		0.004		0.619	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	46.16 (11.095)	45.56 (10.678)	40.91 (10.452)	42.99 (12.266)	
Median	45.68	45.68	39.59	39.59	
Min, Max	21.3, 63.9	21.3, 63.9	15.3, 63.9	15.3, 63.9	
C7D1 CFB					
n	23	45	36	76	
LS Mean (StdErr) [2]	0.27 (2.091)	6.95 (1.636)	2.24 (1.990)	2.85 (1.440)	
95% CI [2]	-3.91, 4.45	3.68, 10.22	-1.71, 6.18	-0.01, 5.70	
Difference (95% CI) in CFB [2]		6.68 (2.33, 11.02)		0.61 (-3.70, 4.91)	
Hedges'G (95% CI) in CFB		0.62 (0.12, 1.16)		0.05 (-0.35, 0.45)	
p-value [3]		0.003		0.780	
					0.065

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	37	79	
Mean (StdDev)	35.39 (11.499)	36.39 (11.350)	33.00 (10.042)	32.05 (10.066)	
Median	33.61	37.86	32.30	30.99	
Min, Max	13.8, 59.0	15.1, 61.8	14.0, 60.4	10.5, 55.6	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	38.35 (11.655)	40.46 (12.018)	35.14 (10.248)	35.66 (11.786)	
Median	35.38	41.96	36.13	35.81	
Min, Max	16.5, 61.2	16.6, 58.5	16.9, 60.0	13.0, 56.1	
C2D1 CFB					
n	28	54	37	77	
LS Mean (StdErr) [2]	0.79 (1.469)	2.55 (1.149)	1.28 (1.210)	2.42 (0.909)	
95% CI [2]	-2.14, 3.71	0.26, 4.83	-1.12, 3.67	0.62, 4.22	
Difference (95% CI) in CFB [2]		1.76 (-1.45, 4.97)		1.14 (-1.47, 3.75)	
p-value [3]		0.278		0.387	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	52	37	76	
Mean (StdDev)	37.08 (10.380)	41.51 (11.589)	35.43 (10.144)	36.89 (12.228)	
Median	36.53	43.19	35.15	36.69	
Min, Max	15.1, 62.6	19.4, 59.9	17.4, 60.0	13.3, 61.4	
C3D1 CFB					
n	27	49	36	75	
LS Mean (StdErr) [2]	1.68 (1.528)	5.60 (1.207)	1.45 (1.234)	3.60 (0.905)	
95% CI [2]	-1.36, 4.73	3.19, 8.00	-1.00, 3.89	1.81, 5.40	
Difference (95% CI) in CFB [2]		3.92 (0.56, 7.27)		2.16 (-0.52, 4.83)	
p-value [3]		0.023		0.113	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	50	37	76	
Mean (StdDev)	38.33 (12.454)	42.18 (10.720)	35.59 (9.297)	36.90 (11.792)	
Median	38.03	44.08	36.16	37.20	
Min, Max	10.8, 61.5	16.2, 59.8	19.8, 57.9	12.8, 59.1	
C4D1 CFB					
n	20	47	36	74	
LS Mean (StdErr) [2]	2.80 (1.764)	5.29 (1.371)	1.61 (1.409)	3.59 (1.056)	
95% CI [2]	-0.73, 6.33	2.55, 8.03	-1.18, 4.40	1.50, 5.69	
Difference (95% CI) in CFB [2]		2.49 (-1.12, 6.11)		1.98 (-1.07, 5.03)	
p-value [3]		0.173		0.200	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	37	78	
Mean (StdDev)	37.22 (12.898)	41.55 (11.349)	36.22 (9.900)	37.30 (12.353)	
Median	40.59	39.65	36.03	38.81	
Min, Max	13.5, 60.1	17.8, 62.4	18.5, 52.9	13.0, 64.3	
C5D1 CFB					
n	25	42	36	76	
LS Mean (StdErr) [2]	1.86 (1.398)	6.16 (1.143)	1.93 (1.468)	3.64 (1.080)	
95% CI [2]	-0.93, 4.66	3.88, 8.45	-0.98, 4.84	1.50, 5.78	
Difference (95% CI) in CFB [2]		4.30 (1.24, 7.35)		1.71 (-1.46, 4.88)	
p-value [3]		0.007		0.288	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	36	77	
Mean (StdDev)	36.26 (11.578)	43.61 (10.376)	35.30 (10.896)	38.31 (12.412)	
Median	33.92	46.57	35.03	37.76	
Min, Max	16.9, 58.8	17.5, 61.0	16.4, 58.5	17.3, 59.1	
C6D1 CFB					
n	23	47	35	75	
LS Mean (StdErr) [2]	0.52 (1.661)	7.11 (1.272)	0.96 (1.451)	4.57 (1.058)	
95% CI [2]	-2.79, 3.84	4.57, 9.65	-1.92, 3.84	2.47, 6.67	
Difference (95% CI) in CFB [2]		6.59 (2.96, 10.21)		3.61 (0.46, 6.76)	
p-value [3]		<0.001		0.025	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	39.25 (12.067)	44.16 (10.851)	36.34 (10.135)	37.09 (12.363)	
Median	39.39	42.94	36.03	36.64	
Min, Max	19.0, 58.2	17.8, 63.1	14.5, 63.2	12.5, 60.6	
C7D1 CFB					
n	23	45	36	75	
LS Mean (StdErr) [2]	1.66 (1.795)	6.41 (1.404)	1.87 (1.504)	3.11 (1.103)	
95% CI [2]	-1.93, 5.24	3.61, 9.22	-1.11, 4.86	0.93, 5.30	
Difference (95% CI) in CFB [2]		4.76 (1.03, 8.49)		1.24 (-2.02, 4.49)	
Hedges'G (95% CI) in CFB		0.51 (0.01, 1.05)		0.13 (-0.27, 0.54)	
p-value [3]		0.013		0.453	
					0.166

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
Baseline					
n	30	55	37	79	
Mean (StdDev)	43.63 (10.405)	39.35 (10.416)	38.86 (10.528)	41.46 (10.556)	
Median	42.14	38.58	37.71	42.34	
Min, Max	23.2, 58.7	18.0, 64.0	19.2, 63.9	13.2, 63.9	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C2D1					
n	31	59	38	78	
Mean (StdDev)	44.68 (10.363)	42.43 (10.730)	40.85 (11.183)	42.63 (10.196)	
Median	45.65	42.34	40.90	42.93	
Min, Max	19.9, 60.7	19.6, 64.8	20.8, 64.4	19.0, 62.5	
C2D1 CFB					
n	28	54	37	77	
LS Mean (StdErr) [2]	1.92 (1.522)	4.56 (1.190)	2.16 (1.477)	1.64 (1.109)	
95% CI [2]	-1.11, 4.95	2.19, 6.93	-0.77, 5.08	-0.55, 3.84	
Difference (95% CI) in CFB [2]		2.65 (-0.67, 5.97)		-0.51 (-3.70, 2.68)	
p-value [3]		0.116		0.751	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C3D1					
n	30	52	37	76	
Mean (StdDev)	47.01 (10.494)	42.15 (11.420)	41.20 (10.521)	44.16 (9.936)	
Median	49.33	43.55	41.60	46.61	
Min, Max	22.9, 60.6	17.7, 60.6	11.2, 63.3	13.8, 66.0	
C3D1 CFB					
n	27	49	36	75	
LS Mean (StdErr) [2]	3.34 (1.719)	4.07 (1.358)	2.71 (1.482)	3.14 (1.087)	
95% CI [2]	-0.09, 6.77	1.36, 6.77	-0.23, 5.65	0.99, 5.30	
Difference (95% CI) in CFB [2]		0.73 (-3.05, 4.50)		0.44 (-2.77, 3.64)	
p-value [3]		0.703		0.788	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C4D1					
n	23	50	37	76	
Mean (StdDev)	45.16 (9.202)	44.33 (10.168)	40.59 (10.303)	44.28 (11.212)	
Median	44.26	45.80	40.11	44.67	
Min, Max	24.2, 58.4	24.3, 60.6	22.0, 59.7	13.7, 63.9	
C4D1 CFB					
n	20	47	36	74	
LS Mean (StdErr) [2]	2.02 (2.226)	5.12 (1.729)	2.45 (1.704)	3.85 (1.277)	
95% CI [2]	-2.43, 6.47	1.66, 8.58	-0.93, 5.83	1.32, 6.39	
Difference (95% CI) in CFB [2]		3.10 (-1.46, 7.66)		1.41 (-2.28, 5.09)	
p-value [3]		0.179		0.452	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C5D1					
n	27	47	37	78	
Mean (StdDev)	47.83 (10.123)	45.00 (10.480)	39.73 (11.595)	44.41 (10.581)	
Median	49.25	46.62	39.39	45.37	
Min, Max	27.1, 61.5	22.4, 62.4	14.1, 61.6	19.5, 64.4	
C5D1 CFB					
n	25	42	36	76	
LS Mean (StdErr) [2]	3.90 (1.973)	5.39 (1.614)	0.99 (1.875)	3.68 (1.379)	
95% CI [2]	-0.05, 7.84	2.16, 8.62	-2.73, 4.71	0.95, 6.42	
Difference (95% CI) in CFB [2]		1.49 (-2.82, 5.81)		2.69 (-1.36, 6.74)	
p-value [3]		0.492		0.191	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C6D1					
n	25	52	36	77	
Mean (StdDev)	47.07 (10.370)	45.52 (10.069)	40.79 (10.020)	42.74 (11.301)	
Median	49.13	46.20	39.24	43.31	
Min, Max	28.3, 61.2	16.6, 61.5	24.1, 61.4	12.1, 61.4	
C6D1 CFB					
n	23	47	35	75	
LS Mean (StdErr) [2]	2.33 (1.956)	5.84 (1.499)	2.24 (1.841)	2.20 (1.342)	
95% CI [2]	-1.58, 6.24	2.85, 8.83	-1.41, 5.89	-0.46, 4.86	
Difference (95% CI) in CFB [2]		3.51 (-0.76, 7.78)		-0.03 (-4.03, 3.96)	
p-value [3]		0.106		0.987	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.3a
Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Region = North America		Region = Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	Test of Interaction p-value [1]
C7D1					
n	25	50	37	77	
Mean (StdDev)	47.10 (9.341)	44.95 (10.721)	40.46 (12.119)	43.79 (11.769)	
Median	48.67	44.55	41.40	45.21	
Min, Max	32.5, 64.6	19.6, 62.0	12.1, 64.9	12.0, 63.3	
C7D1 CFB					
n	23	45	36	75	
LS Mean (StdErr) [2]	0.90 (1.907)	5.49 (1.492)	1.97 (1.875)	2.93 (1.375)	
95% CI [2]	-2.91, 4.71	2.51, 8.47	-1.75, 5.69	0.21, 5.66	
Difference (95% CI) in CFB [2]		4.59 (0.63, 8.55)		0.96 (-3.10, 5.02)	
Hedges'G (95% CI) in CFB		0.47 (-0.04, 1.00)		0.08 (-0.32, 0.49)	
p-value [3]		0.024		0.640	
					0.235

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-reg-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score						
	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score			
	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score						
	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score						
	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score						
	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Country = BEL		Country = CAN		Country = CHE	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=5)	Avapritinib 25 mg (N=8)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Country = DEU		Country = DNK		Country = ESP	
	Placebo (N=15)	Avapritinib 25 mg (N=19)	Placebo (N=0)	Avapritinib 25 mg (N=1)	Placebo (N=3)	Avapritinib 25 mg (N=14)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Country = FRA		Country = GBR		Country = ITA	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=0)	Avapritinib 25 mg (N=4)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Country = NLD		Country = NOR		Country = SWE	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)	Placebo (N=1)	Avapritinib 25 mg (N=2)

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.4a
Change from Baseline of SF-12 by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Country = USA		
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Test of Interaction p-value [1]

By Country subgroup analysis is not performed due to several countries have less than 10 patients.

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-cou-a.sas Date: 15:56/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	23	49	44	85	
Mean (StdDev)	41.15 (10.957)	43.12 (12.256)	36.43 (12.469)	34.14 (9.764)	
Median	39.69	48.10	31.27	31.27	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	43.39 (10.884)	45.07 (11.373)	38.54 (10.977)	37.90 (11.619)	
Median	39.69	48.10	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C2D1 CFB					
n	22	48	43	83	
LS Mean (StdErr) [2]	1.07 (1.685)	1.53 (1.098)	2.41 (1.248)	3.32 (1.007)	
95% CI [2]	-2.30, 4.43	-0.66, 3.72	-0.06, 4.88	1.33, 5.31	
Difference (95% CI) in CFB [2]		0.46 (-2.96, 3.89)		0.91 (-1.97, 3.79)	
p-value [3]		0.788		0.533	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	78	
Mean (StdDev)	41.98 (10.445)	46.17 (11.281)	38.56 (10.398)	37.85 (11.637)	
Median	39.69	48.10	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C3D1 CFB					
n	19	47	44	77	
LS Mean (StdErr) [2]	1.68 (1.897)	3.25 (1.184)	2.00 (1.278)	3.92 (1.054)	
95% CI [2]	-2.12, 5.47	0.88, 5.62	-0.53, 4.53	1.83, 6.01	
Difference (95% CI) in CFB [2]		1.57 (-2.30, 5.45)		1.92 (-1.06, 4.90)	
p-value [3]		0.420		0.205	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	42.49 (10.753)	46.45 (10.285)	38.39 (10.840)	38.33 (11.402)	
Median	39.69	48.10	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C4D1 CFB					
n	18	44	38	80	
LS Mean (StdErr) [2]	2.76 (2.238)	4.54 (1.449)	3.31 (1.454)	4.67 (1.115)	
95% CI [2]	-1.72, 7.24	1.64, 7.44	0.43, 6.19	2.46, 6.88	
Difference (95% CI) in CFB [2]		1.78 (-2.73, 6.28)		1.36 (-1.93, 4.64)	
p-value [3]		0.434		0.415	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	41	78	
Mean (StdDev)	43.34 (11.296)	46.23 (10.895)	38.66 (12.365)	38.71 (11.344)	
Median	48.10	48.10	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C5D1 CFB					
n	20	42	41	76	
LS Mean (StdErr) [2]	1.39 (2.348)	3.02 (1.578)	2.70 (1.386)	5.57 (1.097)	
95% CI [2]	-3.31, 6.08	-0.14, 6.17	-0.05, 5.45	3.40, 7.75	
Difference (95% CI) in CFB [2]		1.63 (-3.13, 6.39)		2.87 (-0.33, 6.08)	
p-value [3]		0.495		0.078	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	42.25 (11.184)	46.35 (11.508)	37.53 (11.209)	40.00 (12.084)	
Median	39.69	48.10	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C6D1 CFB					
n	20	45	39	77	
LS Mean (StdErr) [2]	0.41 (2.143)	3.85 (1.396)	1.30 (1.433)	5.47 (1.112)	
95% CI [2]	-3.87, 4.70	1.06, 6.64	-1.54, 4.14	3.27, 7.68	
Difference (95% CI) in CFB [2]		3.44 (-0.92, 7.79)		4.17 (0.87, 7.48)	
p-value [3]		0.120		0.014	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	41.60 (12.435)	45.12 (12.086)	39.05 (10.675)	39.90 (12.053)	
Median	39.69	48.10	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C7D1 CFB					
n	19	45	40	75	
LS Mean (StdErr) [2]	-0.92 (2.891)	1.25 (1.898)	2.13 (1.442)	5.87 (1.138)	
95% CI [2]	-6.70, 4.86	-2.54, 5.05	-0.72, 4.99	3.62, 8.13	
Difference (95% CI) in CFB [2]		2.17 (-3.62, 7.97)		3.74 (0.45, 7.02)	
Hedges'G (95% CI) in CFB		0.17 (-0.37, 0.72)		0.39 (0.00, 0.79)	
p-value [3]		0.456		0.026	
					0.553

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	23	49	44	85	
Mean (StdDev)	35.10 (8.699)	38.82 (8.643)	34.31 (7.307)	32.51 (7.883)	
Median	34.51	39.00	32.27	30.03	
Min, Max	21.0, 52.5	21.0, 57.0	21.0, 48.0	21.0, 48.0	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	38.47 (9.552)	41.07 (9.303)	35.23 (9.131)	35.41 (9.913)	
Median	39.00	39.00	34.51	34.51	
Min, Max	21.0, 57.0	25.5, 57.0	21.0, 57.0	21.0, 57.0	
C2D1 CFB					
n	22	48	43	83	
LS Mean (StdErr) [2]	1.68 (1.497)	1.18 (0.976)	0.40 (1.225)	2.29 (0.988)	
95% CI [2]	-1.31, 4.67	-0.77, 3.13	-2.03, 2.82	0.34, 4.25	
Difference (95% CI) in CFB [2]		-0.50 (-3.54, 2.54)		1.89 (-0.93, 4.72)	
p-value [3]		0.743		0.187	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	78	
Mean (StdDev)	38.39 (8.903)	42.84 (9.073)	36.01 (10.038)	36.99 (10.476)	
Median	39.00	43.49	34.51	39.00	
Min, Max	25.5, 57.0	21.0, 57.0	21.0, 57.0	21.0, 57.0	
C3D1 CFB					
n	19	47	44	77	
LS Mean (StdErr) [2]	1.14 (2.022)	2.53 (1.262)	1.70 (1.206)	5.10 (0.995)	
95% CI [2]	-2.90, 5.18	0.01, 5.06	-0.69, 4.09	3.13, 7.07	
Difference (95% CI) in CFB [2]		1.39 (-2.74, 5.52)		3.40 (0.58, 6.21)	
p-value [3]		0.504		0.018	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	79	
Mean (StdDev)	38.58 (10.228)	42.52 (9.074)	36.01 (9.950)	38.32 (10.761)	
Median	39.00	43.49	34.51	39.00	
Min, Max	21.0, 57.0	30.0, 57.0	21.0, 57.0	21.0, 57.0	
C4D1 CFB					
n	18	44	38	78	
LS Mean (StdErr) [2]	1.80 (2.116)	3.03 (1.370)	2.41 (1.346)	5.73 (1.053)	
95% CI [2]	-2.43, 6.04	0.29, 5.78	-0.26, 5.08	3.64, 7.81	
Difference (95% CI) in CFB [2]		1.23 (-3.03, 5.50)		3.32 (0.27, 6.36)	
p-value [3]		0.565		0.033	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	41	78	
Mean (StdDev)	39.59 (10.424)	42.60 (7.927)	35.83 (8.591)	37.57 (10.596)	
Median	39.00	43.49	39.00	39.00	
Min, Max	21.0, 57.0	25.5, 57.0	21.0, 52.5	21.0, 57.0	
C5D1 CFB					
n	20	42	41	76	
LS Mean (StdErr) [2]	2.70 (2.356)	3.57 (1.584)	1.83 (1.175)	5.34 (0.930)	
95% CI [2]	-2.01, 7.42	0.40, 6.74	-0.50, 4.16	3.50, 7.19	
Difference (95% CI) in CFB [2]		0.87 (-3.91, 5.64)		3.52 (0.80, 6.23)	
p-value [3]		0.718		0.012	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	37.44 (9.911)	43.12 (8.065)	35.32 (9.925)	39.23 (11.204)	
Median	39.00	43.49	34.51	39.00	
Min, Max	21.0, 57.0	25.5, 57.0	21.0, 57.0	21.0, 57.0	
C6D1 CFB					
n	20	45	39	77	
LS Mean (StdErr) [2]	0.84 (2.249)	3.80 (1.465)	1.03 (1.385)	6.31 (1.075)	
95% CI [2]	-3.66, 5.33	0.88, 6.73	-1.71, 3.78	4.18, 8.44	
Difference (95% CI) in CFB [2]		2.97 (-1.60, 7.53)		5.28 (2.08, 8.47)	
p-value [3]		0.199		0.001	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	39.00 (11.756)	43.03 (9.226)	37.43 (9.727)	38.65 (11.230)	
Median	39.00	43.49	39.00	39.00	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 57.0	21.0, 57.0	
C7D1 CFB					
n	19	45	40	75	
LS Mean (StdErr) [2]	2.69 (2.616)	2.73 (1.717)	2.37 (1.380)	6.06 (1.090)	
95% CI [2]	-2.54, 7.92	-0.71, 6.16	-0.37, 5.10	3.90, 8.22	
Difference (95% CI) in CFB [2]		0.03 (-5.21, 5.28)		3.69 (0.54, 6.83)	
Hedges'G (95% CI) in CFB		0.00 (-0.54, 0.55)		0.40 (0.01, 0.80)	
p-value [3]		0.989		0.022	
					0.165

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	23	49	44	84	
Mean (StdDev)	36.27 (11.165)	38.57 (11.341)	30.43 (10.246)	28.44 (10.161)	
Median	36.27	36.27	26.00	26.00	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	38.32 (12.579)	42.84 (12.233)	34.40 (10.453)	36.27 (12.173)	
Median	36.27	46.54	36.27	36.27	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C2D1 CFB					
n	22	48	43	82	
LS Mean (StdErr) [2]	-0.06 (2.244)	3.62 (1.462)	3.49 (1.697)	6.23 (1.392)	
95% CI [2]	-4.54, 4.42	0.70, 6.54	0.13, 6.85	3.47, 8.98	
Difference (95% CI) in CFB [2]		3.68 (-0.88, 8.24)		2.74 (-1.19, 6.66)	
p-value [3]		0.112		0.170	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	78	
Mean (StdDev)	38.60 (11.398)	43.76 (11.746)	35.81 (11.156)	37.06 (11.677)	
Median	36.27	46.54	36.27	36.27	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C3D1 CFB					
n	19	47	44	76	
LS Mean (StdErr) [2]	2.53 (2.521)	5.58 (1.573)	5.59 (1.482)	9.47 (1.243)	
95% CI [2]	-2.50, 7.57	2.44, 8.72	2.66, 8.53	7.01, 11.93	
Difference (95% CI) in CFB [2]		3.05 (-2.10, 8.20)		3.88 (0.42, 7.34)	
p-value [3]		0.242		0.028	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	45	39	81	
Mean (StdDev)	39.20 (9.268)	43.80 (11.462)	34.69 (11.186)	36.78 (12.776)	
Median	36.27	46.54	36.27	36.27	
Min, Max	26.0, 56.8	26.0, 56.8	15.7, 56.8	15.7, 56.8	
C4D1 CFB					
n	18	43	38	79	
LS Mean (StdErr) [2]	0.45 (3.138)	4.27 (2.093)	4.40 (1.665)	7.55 (1.300)	
95% CI [2]	-5.83, 6.73	0.08, 8.46	1.10, 7.70	4.97, 10.12	
Difference (95% CI) in CFB [2]		3.82 (-2.42, 10.07)		3.15 (-0.62, 6.91)	
p-value [3]		0.225		0.100	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	41	78	
Mean (StdDev)	38.50 (13.483)	43.80 (11.036)	34.77 (11.147)	36.66 (13.492)	
Median	36.27	46.54	36.27	36.27	
Min, Max	15.7, 56.8	26.0, 56.8	15.7, 56.8	15.7, 56.8	
C5D1 CFB					
n	20	42	41	75	
LS Mean (StdErr) [2]	-0.93 (2.806)	4.30 (1.886)	4.16 (1.711)	7.82 (1.376)	
95% CI [2]	-6.55, 4.68	0.52, 8.07	0.77, 7.55	5.10, 10.55	
Difference (95% CI) in CFB [2]		5.23 (-0.46, 10.92)		3.67 (-0.29, 7.63)	
p-value [3]		0.071		0.069	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	38	79	
Mean (StdDev)	36.71 (13.667)	44.61 (10.731)	34.65 (12.298)	37.44 (13.359)	
Median	36.27	46.54	36.27	36.27	
Min, Max	15.7, 56.8	26.0, 56.8	15.7, 56.8	15.7, 56.8	
C6D1 CFB					
n	20	45	38	76	
LS Mean (StdErr) [2]	-2.18 (2.718)	5.96 (1.770)	4.22 (1.757)	8.36 (1.375)	
95% CI [2]	-7.61, 3.26	2.42, 9.50	0.74, 7.70	5.64, 11.09	
Difference (95% CI) in CFB [2]		8.14 (2.61, 13.66)		4.14 (0.09, 8.20)	
p-value [3]		0.005		0.045	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	39.54 (12.830)	42.90 (12.798)	36.78 (10.645)	37.47 (13.533)	
Median	36.27	46.54	36.27	36.27	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C7D1 CFB					
n	19	45	40	74	
LS Mean (StdErr) [2]	0.42 (2.706)	1.85 (1.776)	4.41 (1.769)	7.48 (1.420)	
95% CI [2]	-4.99, 5.83	-1.70, 5.40	0.90, 7.91	4.66, 10.29	
Difference (95% CI) in CFB [2]		1.43 (-3.99, 6.86)		3.07 (-0.96, 7.11)	
Hedges'G (95% CI) in CFB		0.12 (-0.42, 0.67)		0.26 (-0.13, 0.65)	
p-value [3]		0.599		0.134	
					0.578

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	23	49	44	85	
Mean (StdDev)	34.57 (11.625)	37.85 (9.788)	33.43 (9.820)	31.55 (8.850)	
Median	30.05	44.92	30.05	30.05	
Min, Max	19.4, 61.9	19.4, 55.5	19.4, 55.5	19.4, 55.5	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	37.61 (10.677)	39.73 (10.585)	35.41 (11.021)	33.44 (10.195)	
Median	30.05	44.92	30.05	30.05	
Min, Max	19.4, 55.5	19.4, 55.5	19.4, 55.5	19.4, 55.5	
C2D1 CFB					
n	22	48	43	83	
LS Mean (StdErr) [2]	1.69 (2.115)	1.61 (1.378)	1.89 (1.350)	2.07 (1.089)	
95% CI [2]	-2.54, 5.91	-1.14, 4.36	-0.78, 4.56	-0.08, 4.23	
Difference (95% CI) in CFB [2]		-0.07 (-4.37, 4.22)		0.18 (-2.93, 3.30)	
p-value [3]		0.972		0.907	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	78	
Mean (StdDev)	35.45 (8.911)	41.11 (10.032)	35.05 (10.586)	35.14 (11.150)	
Median	30.05	44.92	30.05	30.05	
Min, Max	19.4, 55.5	19.4, 55.5	19.4, 55.5	19.4, 61.9	
C3D1 CFB					
n	19	47	44	77	
LS Mean (StdErr) [2]	-0.17 (1.888)	2.94 (1.178)	0.79 (1.559)	3.81 (1.286)	
95% CI [2]	-3.94, 3.60	0.59, 5.29	-2.30, 3.88	1.26, 6.35	
Difference (95% CI) in CFB [2]		3.11 (-0.75, 6.97)		3.02 (-0.62, 6.66)	
p-value [3]		0.112		0.103	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	38.44 (11.171)	41.27 (10.102)	34.68 (10.280)	35.21 (11.039)	
Median	30.05	44.92	30.05	30.05	
Min, Max	19.4, 61.9	19.4, 55.5	19.4, 55.5	19.4, 55.5	
C4D1 CFB					
n	18	44	38	80	
LS Mean (StdErr) [2]	-0.20 (2.464)	1.86 (1.595)	1.27 (1.624)	3.28 (1.246)	
95% CI [2]	-5.13, 4.73	-1.33, 5.05	-1.95, 4.49	0.81, 5.74	
Difference (95% CI) in CFB [2]		2.06 (-2.91, 7.02)		2.00 (-1.66, 5.67)	
p-value [3]		0.410		0.281	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	41	78	
Mean (StdDev)	38.36 (9.692)	41.05 (9.633)	35.18 (10.266)	35.96 (10.977)	
Median	30.05	44.92	30.05	30.05	
Min, Max	30.0, 61.9	19.4, 55.5	19.4, 55.5	19.4, 55.5	
C5D1 CFB					
n	20	42	41	76	
LS Mean (StdErr) [2]	0.71 (2.548)	2.85 (1.712)	2.15 (1.547)	4.22 (1.224)	
95% CI [2]	-4.39, 5.81	-0.58, 6.27	-0.92, 5.21	1.79, 6.64	
Difference (95% CI) in CFB [2]		2.13 (-3.03, 7.30)		2.07 (-1.51, 5.64)	
p-value [3]		0.411		0.255	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	37.62 (11.474)	41.60 (9.838)	35.44 (11.124)	36.71 (11.328)	
Median	44.92	44.92	30.05	30.05	
Min, Max	19.4, 61.9	19.4, 55.5	19.4, 55.5	19.4, 55.5	
C6D1 CFB					
n	20	45	39	77	
LS Mean (StdErr) [2]	-0.62 (2.470)	3.64 (1.609)	2.51 (1.557)	5.05 (1.208)	
95% CI [2]	-5.56, 4.32	0.43, 6.86	-0.58, 5.59	2.66, 7.45	
Difference (95% CI) in CFB [2]		4.26 (-0.76, 9.28)		2.55 (-1.04, 6.14)	
p-value [3]		0.094		0.163	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	37.96 (11.053)	41.73 (9.780)	35.94 (10.806)	37.03 (11.273)	
Median	37.48	44.92	30.05	44.92	
Min, Max	19.4, 55.5	19.4, 55.5	19.4, 55.5	19.4, 55.5	
C7D1 CFB					
n	19	45	40	75	
LS Mean (StdErr) [2]	-0.06 (2.379)	3.21 (1.562)	1.65 (1.685)	4.83 (1.331)	
95% CI [2]	-4.82, 4.70	0.08, 6.33	-1.69, 4.99	2.19, 7.47	
Difference (95% CI) in CFB [2]		3.27 (-1.50, 8.03)		3.18 (-0.66, 7.02)	
Hedges'G (95% CI) in CFB		0.31 (-0.23, 0.87)		0.28 (-0.10, 0.68)	
p-value [3]		0.176		0.103	
					0.990

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	23	49	44	85	
Mean (StdDev)	37.83 (8.563)	39.05 (8.868)	40.24 (9.067)	36.76 (8.036)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 57.8	28.5, 57.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	41.76 (10.105)	42.35 (9.469)	40.24 (8.303)	38.36 (9.338)	
Median	38.25	48.00	38.25	38.25	
Min, Max	28.5, 67.5	28.5, 57.8	28.5, 57.8	28.5, 57.8	
C2D1 CFB					
n	22	48	43	83	
LS Mean (StdErr) [2]	3.52 (1.665)	3.97 (1.085)	-0.20 (1.380)	1.50 (1.114)	
95% CI [2]	0.20, 6.84	1.80, 6.13	-2.93, 2.53	-0.70, 3.71	
Difference (95% CI) in CFB [2]		0.45 (-2.94, 3.83)		1.70 (-1.48, 4.89)	
p-value [3]		0.793		0.293	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	78	
Mean (StdDev)	40.47 (8.478)	42.92 (10.058)	42.15 (10.059)	39.50 (9.608)	
Median	38.25	48.00	38.25	38.25	
Min, Max	28.5, 67.5	28.5, 57.8	28.5, 57.8	28.5, 57.8	
C3D1 CFB					
n	19	47	44	77	
LS Mean (StdErr) [2]	3.17 (1.915)	4.30 (1.195)	1.84 (1.336)	2.58 (1.102)	
95% CI [2]	-0.66, 6.99	1.91, 6.69	-0.81, 4.48	0.39, 4.76	
Difference (95% CI) in CFB [2]		1.13 (-2.78, 5.05)		0.74 (-2.38, 3.86)	
p-value [3]		0.565		0.640	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	39.18 (9.204)	42.49 (10.000)	40.75 (8.288)	40.30 (10.428)	
Median	38.25	48.00	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 57.8	28.5, 57.8	
C4D1 CFB					
n	18	44	38	80	
LS Mean (StdErr) [2]	1.37 (2.063)	3.02 (1.335)	0.89 (1.712)	2.76 (1.313)	
95% CI [2]	-2.76, 5.50	0.34, 5.69	-2.51, 4.28	0.16, 5.36	
Difference (95% CI) in CFB [2]		1.65 (-2.51, 5.80)		1.87 (-1.99, 5.74)	
p-value [3]		0.431		0.339	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	41	78	
Mean (StdDev)	39.95 (9.598)	42.37 (9.413)	41.10 (9.316)	40.88 (10.269)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 57.8	28.5, 67.5	
C5D1 CFB					
n	20	42	41	76	
LS Mean (StdErr) [2]	3.59 (2.239)	4.68 (1.505)	0.88 (1.609)	3.50 (1.273)	
95% CI [2]	-0.89, 8.07	1.67, 7.69	-2.31, 4.06	0.97, 6.02	
Difference (95% CI) in CFB [2]		1.09 (-3.45, 5.63)		2.62 (-1.10, 6.34)	
p-value [3]		0.633		0.165	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	38.25 (9.300)	44.14 (9.381)	40.00 (8.915)	41.58 (10.347)	
Median	38.25	48.00	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 57.8	28.5, 67.5	
C6D1 CFB					
n	20	45	39	77	
LS Mean (StdErr) [2]	1.54 (2.083)	5.98 (1.357)	-0.28 (1.544)	3.79 (1.199)	
95% CI [2]	-2.62, 5.70	3.27, 8.70	-3.34, 2.77	1.42, 6.17	
Difference (95% CI) in CFB [2]		4.44 (0.21, 8.68)		4.08 (0.52, 7.64)	
p-value [3]		0.040		0.025	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	38.69 (10.633)	43.13 (9.650)	43.13 (10.122)	41.29 (10.878)	
Median	38.25	48.00	48.00	38.25	
Min, Max	28.5, 67.5	28.5, 57.8	28.5, 57.8	28.5, 67.5	
C7D1 CFB					
n	19	45	40	75	
LS Mean (StdErr) [2]	3.06 (1.921)	5.36 (1.261)	2.54 (1.646)	3.49 (1.300)	
95% CI [2]	-0.78, 6.90	2.83, 7.88	-0.72, 5.81	0.91, 6.06	
Difference (95% CI) in CFB [2]		2.29 (-1.56, 6.14)		0.94 (-2.81, 4.69)	
Hedges'G (95% CI) in CFB		0.27 (-0.27, 0.83)		0.09 (-0.30, 0.47)	
p-value [3]		0.238		0.620	
					0.544

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	23	49	44	85	
Mean (StdDev)	41.03 (10.724)	41.75 (9.718)	34.93 (11.826)	35.12 (11.180)	
Median	36.29	36.29	36.29	36.29	
Min, Max	16.5, 56.1	26.4, 56.1	16.5, 56.1	16.5, 56.1	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	41.84 (11.114)	44.61 (9.257)	38.76 (10.717)	38.62 (11.913)	
Median	46.20	46.20	36.29	36.29	
Min, Max	16.5, 56.1	26.4, 56.1	16.5, 56.1	16.5, 56.1	
C2D1 CFB					
n	22	48	43	83	
LS Mean (StdErr) [2]	1.60 (2.265)	3.52 (1.476)	2.78 (1.702)	2.51 (1.373)	
95% CI [2]	-2.92, 6.12	0.57, 6.46	-0.59, 6.15	-0.20, 5.23	
Difference (95% CI) in CFB [2]		1.91 (-2.69, 6.52)		-0.27 (-4.19, 3.66)	
p-value [3]		0.410		0.894	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	78	
Mean (StdDev)	41.24 (11.345)	44.13 (9.363)	40.69 (11.295)	38.70 (12.600)	
Median	41.24	46.20	36.29	36.29	
Min, Max	16.5, 56.1	26.4, 56.1	16.5, 56.1	16.5, 56.1	
C3D1 CFB					
n	19	47	44	77	
LS Mean (StdErr) [2]	2.50 (2.347)	3.40 (1.465)	5.45 (1.551)	3.48 (1.280)	
95% CI [2]	-2.19, 7.19	0.47, 6.33	2.38, 8.52	0.94, 6.01	
Difference (95% CI) in CFB [2]		0.90 (-3.90, 5.69)		-1.97 (-5.60, 1.65)	
p-value [3]		0.710		0.283	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	42.90 (11.010)	45.34 (8.573)	37.81 (10.798)	38.98 (13.394)	
Median	46.20	46.20	36.29	36.29	
Min, Max	26.4, 56.1	26.4, 56.1	16.5, 56.1	16.5, 56.1	
C4D1 CFB					
n	18	44	38	80	
LS Mean (StdErr) [2]	0.87 (2.432)	3.08 (1.575)	2.80 (1.917)	3.95 (1.471)	
95% CI [2]	-4.00, 5.74	-0.07, 6.24	-1.00, 6.60	1.03, 6.86	
Difference (95% CI) in CFB [2]		2.22 (-2.68, 7.12)		1.14 (-3.19, 5.48)	
p-value [3]		0.369		0.601	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	41	78	
Mean (StdDev)	41.46 (12.277)	47.08 (8.408)	38.70 (11.684)	40.61 (13.038)	
Median	46.20	46.20	36.29	36.29	
Min, Max	26.4, 56.1	26.4, 56.1	16.5, 56.1	16.5, 56.1	
C5D1 CFB					
n	20	42	41	76	
LS Mean (StdErr) [2]	0.45 (2.848)	6.50 (1.914)	3.22 (1.820)	5.01 (1.440)	
95% CI [2]	-5.25, 6.14	2.67, 10.33	-0.39, 6.82	2.15, 7.86	
Difference (95% CI) in CFB [2]		6.05 (0.28, 11.82)		1.79 (-2.42, 5.99)	
p-value [3]		0.040		0.402	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	39.73 (13.237)	46.61 (9.137)	38.83 (10.599)	40.05 (12.927)	
Median	36.29	46.20	36.29	46.20	
Min, Max	16.5, 56.1	26.4, 56.1	16.5, 56.1	16.5, 56.1	
C6D1 CFB					
n	20	45	39	77	
LS Mean (StdErr) [2]	-0.56 (2.796)	5.86 (1.821)	3.03 (1.881)	3.82 (1.461)	
95% CI [2]	-6.15, 5.03	2.22, 9.50	-0.70, 6.76	0.93, 6.72	
Difference (95% CI) in CFB [2]		6.42 (0.74, 12.10)		0.79 (-3.54, 5.13)	
p-value [3]		0.027		0.718	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	43.50 (13.046)	45.58 (10.103)	39.01 (10.996)	40.79 (13.218)	
Median	41.24	46.20	36.29	46.20	
Min, Max	16.5, 56.1	26.4, 56.1	16.5, 56.1	16.5, 56.1	
C7D1 CFB					
n	19	45	40	75	
LS Mean (StdErr) [2]	2.13 (2.808)	4.57 (1.843)	2.46 (1.952)	4.72 (1.541)	
95% CI [2]	-3.48, 7.75	0.88, 8.25	-1.41, 6.32	1.66, 7.77	
Difference (95% CI) in CFB [2]		2.43 (-3.19, 8.06)		2.26 (-2.19, 6.71)	
Hedges'G (95% CI) in CFB		0.20 (-0.35, 0.75)		0.17 (-0.21, 0.56)	
p-value [3]		0.390		0.316	
					0.880

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	23	49	44	85	
Mean (StdDev)	41.19 (11.720)	41.97 (11.159)	35.51 (11.709)	36.02 (11.717)	
Median	39.27	39.27	33.75	33.75	
Min, Max	17.2, 55.8	22.7, 55.8	11.7, 55.8	11.7, 55.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	40.60 (11.738)	44.57 (10.094)	39.90 (11.179)	39.73 (12.288)	
Median	39.27	44.79	39.27	39.27	
Min, Max	17.2, 55.8	17.2, 55.8	22.7, 55.8	11.7, 55.8	
C2D1 CFB					
n	22	48	43	83	
LS Mean (StdErr) [2]	0.75 (2.470)	3.65 (1.610)	5.10 (1.433)	4.49 (1.156)	
95% CI [2]	-4.18, 5.68	0.44, 6.87	2.27, 7.94	2.20, 6.77	
Difference (95% CI) in CFB [2]		2.91 (-2.11, 7.93)		-0.62 (-3.92, 2.69)	
p-value [3]		0.252		0.713	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	78	
Mean (StdDev)	43.79 (10.587)	46.17 (9.827)	39.76 (13.093)	39.48 (12.403)	
Median	44.79	47.55	39.27	36.51	
Min, Max	22.7, 55.8	22.7, 55.8	11.7, 55.8	11.7, 55.8	
C3D1 CFB					
n	19	47	44	77	
LS Mean (StdErr) [2]	1.35 (2.398)	3.87 (1.497)	4.94 (1.571)	5.06 (1.296)	
95% CI [2]	-3.45, 6.14	0.88, 6.87	1.83, 8.05	2.49, 7.63	
Difference (95% CI) in CFB [2]		2.53 (-2.37, 7.43)		0.11 (-3.55, 3.78)	
p-value [3]		0.307		0.951	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	80	
Mean (StdDev)	42.69 (12.399)	46.23 (9.970)	37.86 (11.585)	40.79 (12.541)	
Median	44.79	50.31	33.75	44.79	
Min, Max	17.2, 55.8	17.2, 55.8	17.2, 55.8	11.7, 55.8	
C4D1 CFB					
n	18	44	38	79	
LS Mean (StdErr) [2]	-1.30 (2.883)	3.54 (1.867)	4.68 (1.773)	5.57 (1.364)	
95% CI [2]	-7.07, 4.47	-0.20, 7.27	1.16, 8.19	2.87, 8.27	
Difference (95% CI) in CFB [2]		4.84 (-0.97, 10.65)		0.89 (-3.12, 4.91)	
p-value [3]		0.101		0.660	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	41	78	
Mean (StdDev)	41.43 (11.736)	45.40 (9.575)	40.89 (12.478)	41.82 (11.890)	
Median	44.79	44.79	39.27	44.79	
Min, Max	17.2, 55.8	22.7, 55.8	11.7, 55.8	11.7, 55.8	
C5D1 CFB					
n	20	42	41	76	
LS Mean (StdErr) [2]	-2.26 (2.565)	3.04 (1.724)	6.84 (1.853)	6.69 (1.467)	
95% CI [2]	-7.39, 2.88	-0.41, 6.48	3.17, 10.51	3.79, 9.60	
Difference (95% CI) in CFB [2]		5.29 (0.09, 10.49)		-0.15 (-4.43, 4.14)	
p-value [3]		0.046		0.946	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	39	79	
Mean (StdDev)	41.67 (12.871)	46.05 (9.125)	40.83 (12.971)	40.18 (12.728)	
Median	44.79	44.79	44.79	44.79	
Min, Max	11.7, 55.8	22.7, 55.8	11.7, 55.8	11.7, 55.8	
C6D1 CFB					
n	20	45	39	77	
LS Mean (StdErr) [2]	-1.17 (2.874)	4.15 (1.872)	5.99 (1.953)	4.24 (1.516)	
95% CI [2]	-6.91, 4.58	0.41, 7.89	2.12, 9.86	1.24, 7.25	
Difference (95% CI) in CFB [2]		5.32 (-0.52, 11.16)		-1.75 (-6.25, 2.75)	
p-value [3]		0.073		0.443	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	42.78 (13.789)	45.25 (10.172)	39.13 (12.084)	40.92 (12.212)	
Median	44.79	47.55	36.51	44.79	
Min, Max	11.7, 55.8	17.2, 55.8	11.7, 55.8	11.7, 55.8	
C7D1 CFB					
n	19	45	40	75	
LS Mean (StdErr) [2]	-2.10 (2.589)	2.88 (1.700)	3.22 (1.736)	4.68 (1.371)	
95% CI [2]	-7.28, 3.08	-0.52, 6.28	-0.22, 6.66	1.96, 7.39	
Difference (95% CI) in CFB [2]		4.98 (-0.21, 10.17)		1.45 (-2.50, 5.41)	
Hedges'G (95% CI) in CFB		0.43 (-0.10, 1.00)		0.12 (-0.26, 0.52)	
p-value [3]		0.060		0.468	
					0.288

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	23	49	44	85	
Mean (StdDev)	44.09 (9.569)	42.95 (10.092)	40.01 (9.587)	38.02 (9.896)	
Median	39.59	39.59	39.59	39.59	
Min, Max	33.5, 63.9	21.3, 63.9	21.3, 57.8	15.3, 57.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	44.70 (10.635)	44.46 (9.197)	40.84 (10.211)	40.10 (10.955)	
Median	45.68	45.68	39.59	39.59	
Min, Max	27.4, 63.9	27.4, 63.9	21.3, 57.8	15.3, 57.8	
C2D1 CFB					
n	22	48	43	83	
LS Mean (StdErr) [2]	1.73 (1.787)	2.52 (1.164)	1.13 (1.156)	2.64 (0.933)	
95% CI [2]	-1.83, 5.30	0.19, 4.84	-1.16, 3.42	0.79, 4.48	
Difference (95% CI) in CFB [2]		0.78 (-2.85, 4.41)		1.51 (-1.16, 4.18)	
p-value [3]		0.669		0.265	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	78	
Mean (StdDev)	46.23 (9.738)	47.32 (10.097)	41.35 (10.345)	41.54 (11.026)	
Median	45.68	48.72	39.59	45.68	
Min, Max	27.4, 63.9	21.3, 63.9	15.3, 63.9	15.3, 57.8	
C3D1 CFB					
n	19	47	44	77	
LS Mean (StdErr) [2]	0.94 (2.150)	4.20 (1.342)	1.44 (1.350)	4.02 (1.114)	
95% CI [2]	-3.36, 5.24	1.52, 6.88	-1.23, 4.11	1.81, 6.23	
Difference (95% CI) in CFB [2]		3.26 (-1.14, 7.65)		2.58 (-0.57, 5.73)	
p-value [3]		0.144		0.108	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	46	39	81	
Mean (StdDev)	44.81 (9.673)	47.40 (9.128)	41.62 (9.901)	42.60 (11.547)	
Median	45.68	45.68	39.59	45.68	
Min, Max	27.4, 63.9	21.3, 63.9	21.3, 63.9	15.3, 63.9	
C4D1 CFB					
n	18	44	38	80	
LS Mean (StdErr) [2]	1.12 (2.094)	5.41 (1.355)	2.92 (1.577)	5.18 (1.210)	
95% CI [2]	-3.07, 5.31	2.70, 8.12	-0.20, 6.05	2.78, 7.58	
Difference (95% CI) in CFB [2]		4.29 (0.07, 8.51)		2.26 (-1.30, 5.82)	
p-value [3]		0.046		0.212	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	41	78	
Mean (StdDev)	46.21 (11.143)	46.49 (8.564)	41.23 (10.538)	42.40 (11.165)	
Median	45.68	45.68	39.59	39.59	
Min, Max	27.4, 63.9	27.4, 63.9	21.3, 63.9	15.3, 63.9	
C5D1 CFB					
n	20	42	41	76	
LS Mean (StdErr) [2]	-0.03 (2.098)	3.12 (1.410)	2.22 (1.568)	4.74 (1.241)	
95% CI [2]	-4.23, 4.17	0.30, 5.94	-0.89, 5.32	2.29, 7.20	
Difference (95% CI) in CFB [2]		3.15 (-1.10, 7.40)		2.53 (-1.10, 6.15)	
p-value [3]		0.144		0.170	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	38	79	
Mean (StdDev)	44.09 (10.082)	46.82 (8.753)	42.48 (9.974)	41.44 (11.416)	
Median	45.68	45.68	39.59	45.68	
Min, Max	27.4, 57.8	27.4, 63.9	27.4, 63.9	15.3, 63.9	
C6D1 CFB					
n	20	45	38	77	
LS Mean (StdErr) [2]	-0.57 (1.837)	4.37 (1.197)	2.55 (1.639)	4.25 (1.262)	
95% CI [2]	-4.24, 3.10	1.98, 6.76	-0.70, 5.79	1.75, 6.75	
Difference (95% CI) in CFB [2]		4.94 (1.21, 8.68)		1.70 (-2.08, 5.48)	
p-value [3]		0.010		0.375	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	46.23 (11.092)	46.18 (9.707)	41.27 (10.580)	42.44 (12.660)	
Median	45.68	45.68	42.64	39.59	
Min, Max	27.4, 63.9	27.4, 63.9	15.3, 63.9	15.3, 63.9	
C7D1 CFB					
n	19	45	40	75	
LS Mean (StdErr) [2]	-0.06 (2.273)	2.91 (1.492)	2.10 (1.855)	5.17 (1.465)	
95% CI [2]	-4.61, 4.48	-0.08, 5.89	-1.58, 5.77	2.27, 8.08	
Difference (95% CI) in CFB [2]		2.97 (-1.58, 7.53)		3.07 (-1.16, 7.30)	
Hedges'G (95% CI) in CFB		0.29 (-0.24, 0.85)		0.25 (-0.14, 0.64)	
p-value [3]		0.197		0.153	
					0.894

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	23	49	44	84	
Mean (StdDev)	35.52 (11.422)	39.34 (11.856)	33.32 (10.361)	30.62 (8.762)	
Median	31.70	40.81	33.42	30.57	
Min, Max	14.0, 59.0	10.5, 61.8	13.8, 60.4	11.7, 50.2	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	39.14 (11.532)	42.02 (12.411)	35.12 (10.442)	35.17 (11.277)	
Median	37.56	44.43	35.34	35.58	
Min, Max	20.9, 61.2	17.0, 58.2	16.5, 58.9	13.0, 58.5	
C2D1 CFB					
n	22	48	43	82	
LS Mean (StdErr) [2]	1.01 (1.595)	1.45 (1.039)	1.41 (1.139)	3.36 (0.934)	
95% CI [2]	-2.18, 4.19	-0.63, 3.52	-0.84, 3.67	1.51, 5.21	
Difference (95% CI) in CFB [2]		0.44 (-2.80, 3.68)		1.95 (-0.68, 4.58)	
p-value [3]		0.788		0.145	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	78	
Mean (StdDev)	37.09 (9.957)	42.83 (11.984)	35.72 (10.406)	36.13 (11.712)	
Median	36.89	44.11	35.15	36.46	
Min, Max	18.0, 60.0	14.8, 60.8	15.1, 62.6	13.3, 61.4	
C3D1 CFB					
n	19	47	44	76	
LS Mean (StdErr) [2]	1.48 (1.821)	3.20 (1.136)	1.99 (1.092)	5.42 (0.916)	
95% CI [2]	-2.16, 5.12	0.93, 5.47	-0.17, 4.15	3.60, 7.23	
Difference (95% CI) in CFB [2]		1.72 (-2.00, 5.44)		3.42 (0.87, 5.98)	
p-value [3]		0.359		0.009	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	45	39	79	
Mean (StdDev)	38.78 (10.429)	43.11 (10.931)	35.49 (10.645)	36.49 (11.490)	
Median	36.81	43.58	36.24	39.34	
Min, Max	21.7, 61.5	22.4, 59.1	10.8, 57.9	12.8, 59.8	
C4D1 CFB					
n	18	43	38	77	
LS Mean (StdErr) [2]	1.80 (2.241)	2.85 (1.494)	2.29 (1.226)	5.17 (0.977)	
95% CI [2]	-2.68, 6.29	-0.14, 5.84	-0.14, 4.72	3.24, 7.11	
Difference (95% CI) in CFB [2]		1.04 (-3.42, 5.50)		2.88 (0.11, 5.66)	
p-value [3]		0.641		0.042	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	41	78	
Mean (StdDev)	39.22 (11.316)	43.06 (10.397)	35.19 (10.969)	36.16 (12.328)	
Median	40.60	43.93	36.03	36.64	
Min, Max	19.0, 60.1	20.1, 60.6	13.5, 56.2	13.0, 64.3	
C5D1 CFB					
n	20	42	41	75	
LS Mean (StdErr) [2]	1.96 (2.199)	3.42 (1.478)	1.62 (1.164)	5.22 (0.936)	
95% CI [2]	-2.44, 6.36	0.46, 6.38	-0.69, 3.92	3.36, 7.07	
Difference (95% CI) in CFB [2]		1.46 (-2.99, 5.92)		3.60 (0.91, 6.29)	
p-value [3]		0.514		0.009	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	38	79	
Mean (StdDev)	37.64 (11.082)	43.54 (10.834)	34.52 (11.082)	38.28 (12.129)	
Median	38.56	47.35	33.98	39.57	
Min, Max	19.8, 58.8	18.3, 61.0	16.4, 58.5	17.3, 59.1	
C6D1 CFB					
n	20	45	38	76	
LS Mean (StdErr) [2]	0.02 (2.096)	4.14 (1.365)	1.07 (1.277)	6.55 (0.999)	
95% CI [2]	-4.17, 4.21	1.41, 6.86	-1.46, 3.60	4.57, 8.53	
Difference (95% CI) in CFB [2]		4.11 (-0.14, 8.37)		5.48 (2.53, 8.43)	
p-value [3]		0.058		<0.001	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	38.19 (11.640)	42.75 (11.585)	37.14 (10.692)	37.75 (12.303)	
Median	36.53	41.98	37.41	37.52	
Min, Max	14.5, 58.2	15.4, 63.1	19.0, 63.2	12.5, 60.6	
C7D1 CFB					
n	19	45	40	74	
LS Mean (StdErr) [2]	1.16 (2.374)	1.80 (1.559)	2.37 (1.249)	6.14 (1.003)	
95% CI [2]	-3.59, 5.91	-1.32, 4.92	-0.10, 4.85	4.16, 8.13	
Difference (95% CI) in CFB [2]		0.64 (-4.12, 5.40)		3.77 (0.92, 6.62)	
Hedges'G (95% CI) in CFB		0.06 (-0.48, 0.61)		0.45 (0.06, 0.85)	
p-value [3]		0.789		0.010	
					0.197

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
Baseline					
n	23	49	44	84	
Mean (StdDev)	43.48 (10.369)	42.56 (11.113)	39.69 (10.701)	39.39 (10.079)	
Median	41.94	42.39	38.54	38.69	
Min, Max	27.5, 63.9	18.0, 64.0	19.2, 58.7	13.2, 61.0	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C2D1					
n	25	50	44	85	
Mean (StdDev)	43.49 (10.724)	44.80 (9.997)	42.05 (11.110)	41.11 (10.516)	
Median	45.65	44.53	42.21	40.52	
Min, Max	23.2, 61.7	25.3, 62.5	19.9, 64.4	19.0, 64.8	
C2D1 CFB					
n	22	48	43	82	
LS Mean (StdErr) [2]	1.95 (2.023)	3.81 (1.318)	2.40 (1.236)	2.25 (1.014)	
95% CI [2]	-2.08, 5.99	1.18, 6.44	-0.05, 4.85	0.24, 4.25	
Difference (95% CI) in CFB [2]		1.86 (-2.25, 5.97)		-0.15 (-3.01, 2.71)	
p-value [3]		0.370		0.917	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C3D1					
n	22	48	45	78	
Mean (StdDev)	45.49 (9.438)	46.31 (10.367)	42.98 (11.455)	41.71 (10.439)	
Median	47.53	48.47	43.42	43.55	
Min, Max	22.9, 61.6	21.7, 66.0	11.2, 63.3	13.8, 59.0	
C3D1 CFB					
n	19	47	44	76	
LS Mean (StdErr) [2]	1.69 (2.126)	4.00 (1.327)	3.52 (1.271)	3.09 (1.066)	
95% CI [2]	-2.56, 5.94	1.35, 6.65	1.00, 6.03	0.98, 5.20	
Difference (95% CI) in CFB [2]		2.31 (-2.04, 6.65)		-0.42 (-3.40, 2.55)	
p-value [3]		0.293		0.778	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C4D1					
n	21	45	39	79	
Mean (StdDev)	44.22 (10.229)	46.46 (8.785)	41.33 (9.967)	43.14 (11.736)	
Median	42.78	46.48	41.05	44.41	
Min, Max	24.2, 59.4	23.4, 60.4	22.0, 59.7	13.7, 63.9	
C4D1 CFB					
n	18	43	38	77	
LS Mean (StdErr) [2]	-0.55 (2.278)	3.62 (1.519)	3.16 (1.616)	4.48 (1.288)	
95% CI [2]	-5.11, 4.01	0.58, 6.66	-0.04, 6.36	1.93, 7.03	
Difference (95% CI) in CFB [2]		4.17 (-0.36, 8.71)		1.32 (-2.34, 4.99)	
p-value [3]		0.071		0.476	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C5D1					
n	23	45	41	78	
Mean (StdDev)	43.89 (10.904)	46.24 (8.567)	42.72 (12.138)	43.73 (11.536)	
Median	44.84	46.72	41.22	45.37	
Min, Max	18.6, 59.5	29.9, 64.4	14.1, 61.6	19.5, 62.5	
C5D1 CFB					
n	20	42	41	75	
LS Mean (StdErr) [2]	-0.60 (2.263)	4.08 (1.521)	3.90 (1.678)	4.68 (1.349)	
95% CI [2]	-5.13, 3.93	1.04, 7.13	0.58, 7.23	2.01, 7.36	
Difference (95% CI) in CFB [2]		4.69 (0.10, 9.27)		0.78 (-3.10, 4.67)	
p-value [3]		0.045		0.690	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C6D1					
n	23	48	38	79	
Mean (StdDev)	42.81 (10.509)	46.80 (8.762)	43.70 (10.701)	41.98 (11.738)	
Median	44.30	47.74	39.71	43.15	
Min, Max	24.1, 57.7	26.1, 61.4	25.4, 61.4	12.1, 61.5	
C6D1 CFB					
n	20	45	38	76	
LS Mean (StdErr) [2]	-0.55 (2.084)	4.92 (1.357)	3.94 (1.700)	2.78 (1.330)	
95% CI [2]	-4.71, 3.62	2.20, 7.63	0.58, 7.31	0.14, 5.41	
Difference (95% CI) in CFB [2]		5.47 (1.23, 9.70)		-1.17 (-5.10, 2.76)	
p-value [3]		0.012		0.557	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.5a
Change from Baseline of SF-12 by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Baseline ISM status = Moderate		Baseline ISM status = Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	Test of Interaction p-value [1]
C7D1					
n	22	48	40	77	
Mean (StdDev)	45.12 (10.986)	46.08 (9.744)	42.04 (11.735)	43.00 (12.219)	
Median	46.81	46.86	42.90	43.65	
Min, Max	21.4, 64.9	25.3, 63.3	12.1, 64.6	12.0, 62.7	
C7D1 CFB					
n	19	45	40	74	
LS Mean (StdErr) [2]	0.19 (2.032)	4.30 (1.334)	2.50 (1.739)	3.77 (1.397)	
95% CI [2]	-3.87, 4.26	1.63, 6.96	-0.95, 5.94	1.00, 6.54	
Difference (95% CI) in CFB [2]		4.10 (0.03, 8.17)		1.27 (-2.69, 5.24)	
Hedges'G (95% CI) in CFB		0.45 (-0.08, 1.02)		0.11 (-0.28, 0.50)	
p-value [3]		0.048		0.526	
					0.337

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ism-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	12	27	55	108	
Mean (StdDev)	38.28 (10.041)	35.32 (12.209)	38.00 (12.585)	37.97 (11.316)	
Median	39.69	31.27	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	41.93 (11.229)	38.75 (13.872)	39.84 (11.145)	41.14 (11.503)	
Median	39.69	39.69	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C2D1 CFB					
n	12	26	53	106	
LS Mean (StdErr) [2]	0.86 (2.310)	2.16 (1.398)	2.15 (1.019)	2.80 (0.741)	
95% CI [2]	-3.83, 5.55	-0.67, 5.00	0.14, 4.16	1.33, 4.26	
Difference (95% CI) in CFB [2]		1.31 (-4.01, 6.62)		0.65 (-1.81, 3.10)	
p-value [3]		0.621		0.603	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	102	
Mean (StdDev)	41.37 (10.643)	39.04 (13.018)	39.20 (10.461)	41.58 (11.835)	
Median	39.69	39.69	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C3D1 CFB					
n	12	26	51	99	
LS Mean (StdErr) [2]	1.28 (2.470)	3.86 (1.495)	1.81 (1.088)	3.45 (0.791)	
95% CI [2]	-3.73, 6.30	0.83, 6.90	-0.34, 3.96	1.89, 5.02	
Difference (95% CI) in CFB [2]		2.58 (-3.10, 8.26)		1.64 (-0.97, 4.25)	
p-value [3]		0.363		0.215	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	42.27 (9.335)	40.04 (11.499)	39.15 (11.289)	41.77 (11.714)	
Median	39.69	39.69	39.69	39.69	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C4D1 CFB					
n	10	24	46	101	
LS Mean (StdErr) [2]	2.69 (3.065)	6.01 (1.823)	2.38 (1.212)	3.49 (0.840)	
95% CI [2]	-3.56, 8.94	2.29, 9.73	-0.02, 4.77	1.83, 5.15	
Difference (95% CI) in CFB [2]		3.32 (-3.62, 10.26)		1.11 (-1.75, 3.98)	
p-value [3]		0.336		0.443	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	99	
Mean (StdDev)	42.09 (8.995)	40.66 (13.320)	39.85 (12.889)	41.98 (11.392)	
Median	39.69	39.69	39.69	39.69	
Min, Max	31.3, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C5D1 CFB					
n	11	25	50	94	
LS Mean (StdErr) [2]	1.10 (2.711)	4.30 (1.650)	2.15 (1.218)	4.45 (0.910)	
95% CI [2]	-4.42, 6.62	0.95, 7.66	-0.26, 4.56	2.66, 6.25	
Difference (95% CI) in CFB [2]		3.20 (-2.90, 9.30)		2.31 (-0.65, 5.26)	
p-value [3]		0.293		0.125	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	41.49 (9.999)	40.31 (13.791)	38.63 (11.724)	43.15 (11.742)	
Median	39.69	39.69	39.69	43.89	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C6D1 CFB					
n	11	26	48	97	
LS Mean (StdErr) [2]	-0.14 (2.710)	4.60 (1.608)	1.13 (1.214)	4.88 (0.874)	
95% CI [2]	-5.65, 5.36	1.33, 7.87	-1.27, 3.53	3.15, 6.60	
Difference (95% CI) in CFB [2]		4.74 (-1.38, 10.86)		3.74 (0.82, 6.66)	
p-value [3]		0.125		0.012	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	43.57 (7.380)	40.69 (13.375)	39.00 (12.003)	42.49 (12.094)	
Median	39.69	39.69	39.69	39.69	
Min, Max	31.3, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C7D1 CFB					
n	10	24	49	97	
LS Mean (StdErr) [2]	-0.74 (2.730)	3.45 (1.624)	0.85 (1.373)	3.88 (0.990)	
95% CI [2]	-6.31, 4.83	0.14, 6.76	-1.86, 3.57	1.92, 5.84	
Difference (95% CI) in CFB [2]		4.19 (-1.99, 10.37)		3.03 (-0.27, 6.32)	
Hedges'G (95% CI) in CFB		0.50 (-0.24, 1.32)		0.31 (-0.03, 0.66)	
p-value [3]		0.176		0.072	
					0.923

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	12	27	55	108	
Mean (StdDev)	35.64 (6.935)	34.35 (9.998)	34.35 (7.964)	34.89 (8.351)	
Median	34.51	30.03	30.03	34.51	
Min, Max	21.0, 48.0	21.0, 57.0	21.0, 52.5	21.0, 57.0	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	33.62 (8.173)	36.01 (10.783)	37.18 (9.574)	38.02 (9.944)	
Median	34.51	34.51	36.76	39.00	
Min, Max	21.0, 48.0	21.0, 57.0	21.0, 57.0	21.0, 57.0	
C2D1 CFB					
n	12	26	53	106	
LS Mean (StdErr) [2]	-4.56 (2.178)	1.16 (1.318)	3.08 (0.969)	3.21 (0.704)	
95% CI [2]	-8.98, -0.14	-1.52, 3.84	1.17, 5.00	1.82, 4.60	
Difference (95% CI) in CFB [2]		5.72 (0.71, 10.73)		0.13 (-2.20, 2.46)	
p-value [3]		0.026		0.913	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	102	
Mean (StdDev)	36.31 (9.263)	37.80 (10.123)	36.93 (9.878)	39.58 (10.297)	
Median	39.00	39.00	34.51	39.00	
Min, Max	21.0, 48.0	21.0, 57.0	21.0, 57.0	21.0, 57.0	
C3D1 CFB					
n	12	26	51	99	
LS Mean (StdErr) [2]	-2.86 (2.568)	3.51 (1.554)	2.83 (1.047)	4.81 (0.762)	
95% CI [2]	-8.07, 2.35	0.36, 6.67	0.76, 4.90	3.30, 6.31	
Difference (95% CI) in CFB [2]		6.37 (0.47, 12.28)		1.98 (-0.53, 4.49)	
p-value [3]		0.035		0.121	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	23	47	104	
Mean (StdDev)	37.28 (5.950)	36.27 (9.642)	36.81 (10.952)	40.73 (10.266)	
Median	39.00	34.51	39.00	43.49	
Min, Max	25.5, 48.0	21.0, 57.0	21.0, 57.0	21.0, 57.0	
C4D1 CFB					
n	10	23	46	100	
LS Mean (StdErr) [2]	0.40 (2.084)	3.01 (1.255)	3.16 (1.194)	5.80 (0.830)	
95% CI [2]	-3.85, 4.66	0.45, 5.58	0.80, 5.52	4.16, 7.44	
Difference (95% CI) in CFB [2]		2.61 (-2.16, 7.38)		2.64 (-0.18, 5.47)	
p-value [3]		0.272		0.067	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	99	
Mean (StdDev)	38.36 (6.555)	39.18 (12.408)	36.85 (10.069)	39.73 (9.376)	
Median	39.00	39.00	39.00	39.00	
Min, Max	21.0, 48.0	21.0, 57.0	21.0, 57.0	21.0, 57.0	
C5D1 CFB					
n	11	25	50	94	
LS Mean (StdErr) [2]	-0.05 (2.438)	4.23 (1.484)	2.76 (1.107)	5.05 (0.826)	
95% CI [2]	-5.01, 4.91	1.21, 7.25	0.57, 4.95	3.42, 6.69	
Difference (95% CI) in CFB [2]		4.28 (-1.20, 9.77)		2.29 (-0.39, 4.98)	
p-value [3]		0.122		0.094	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	37.40 (5.166)	38.01 (9.987)	35.73 (10.908)	41.56 (10.216)	
Median	39.00	39.00	34.51	41.25	
Min, Max	30.0, 43.5	21.0, 57.0	21.0, 57.0	21.0, 57.0	
C6D1 CFB					
n	11	26	48	97	
LS Mean (StdErr) [2]	-0.27 (2.286)	3.38 (1.356)	1.98 (1.246)	6.66 (0.897)	
95% CI [2]	-4.91, 4.38	0.62, 6.13	-0.49, 4.44	4.88, 8.43	
Difference (95% CI) in CFB [2]		3.64 (-1.52, 8.81)		4.68 (1.68, 7.68)	
p-value [3]		0.161		0.002	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	38.66 (6.470)	39.00 (12.698)	37.81 (11.290)	40.90 (10.215)	
Median	39.00	39.00	39.00	39.00	
Min, Max	30.0, 52.5	21.0, 57.0	21.0, 57.0	21.0, 57.0	
C7D1 CFB					
n	10	24	49	97	
LS Mean (StdErr) [2]	-0.21 (2.830)	3.30 (1.683)	3.48 (1.266)	5.75 (0.913)	
95% CI [2]	-5.98, 5.56	-0.13, 6.74	0.98, 5.98	3.95, 7.56	
Difference (95% CI) in CFB [2]		3.51 (-2.89, 9.91)		2.27 (-0.77, 5.31)	
Hedges'G (95% CI) in CFB		0.41 (-0.34, 1.21)		0.25 (-0.09, 0.60)	
p-value [3]		0.272		0.142	
					0.982

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	12	26	55	108	
Mean (StdDev)	32.84 (11.021)	32.71 (13.914)	32.35 (10.914)	32.08 (11.060)	
Median	31.13	26.00	26.00	31.13	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	37.64 (12.193)	35.89 (15.202)	35.32 (11.156)	39.16 (11.816)	
Median	36.27	36.27	36.27	36.27	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C2D1 CFB					
n	12	25	53	106	
LS Mean (StdErr) [2]	4.17 (3.484)	1.63 (2.135)	2.94 (1.329)	7.12 (0.966)	
95% CI [2]	-2.91, 11.25	-2.71, 5.97	0.31, 5.56	5.22, 9.03	
Difference (95% CI) in CFB [2]		-2.54 (-10.65, 5.56)		4.18 (0.99, 7.38)	
p-value [3]		0.528		0.011	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	102	
Mean (StdDev)	38.32 (10.416)	40.61 (13.679)	36.27 (11.505)	39.39 (11.633)	
Median	36.27	46.54	36.27	46.54	
Min, Max	26.0, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C3D1 CFB					
n	12	25	51	99	
LS Mean (StdErr) [2]	4.21 (2.964)	7.55 (1.816)	3.79 (1.319)	7.47 (0.960)	
95% CI [2]	-1.81, 10.23	3.86, 11.24	1.18, 6.40	5.57, 9.36	
Difference (95% CI) in CFB [2]		3.34 (-3.56, 10.23)		3.67 (0.51, 6.84)	
p-value [3]		0.332		0.023	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	23	47	105	
Mean (StdDev)	33.90 (9.519)	36.71 (13.311)	36.92 (11.004)	39.69 (12.552)	
Median	36.27	36.27	36.27	46.54	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C4D1 CFB					
n	10	22	46	101	
LS Mean (StdErr) [2]	-1.10 (3.096)	4.41 (1.917)	4.85 (1.540)	7.78 (1.067)	
95% CI [2]	-7.43, 5.23	0.49, 8.33	1.80, 7.89	5.68, 9.89	
Difference (95% CI) in CFB [2]		5.51 (-1.54, 12.56)		2.94 (-0.70, 6.57)	
p-value [3]		0.121		0.113	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	99	
Mean (StdDev)	38.47 (9.167)	38.64 (12.764)	35.45 (12.764)	39.38 (13.160)	
Median	36.27	36.27	36.27	36.27	
Min, Max	26.0, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C5D1 CFB					
n	11	24	50	94	
LS Mean (StdErr) [2]	2.37 (3.204)	4.00 (1.970)	2.90 (1.492)	7.62 (1.114)	
95% CI [2]	-4.16, 8.89	-0.01, 8.02	-0.05, 5.85	5.42, 9.82	
Difference (95% CI) in CFB [2]		1.64 (-5.64, 8.92)		4.72 (1.10, 8.34)	
p-value [3]		0.650		0.011	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	47	102	
Mean (StdDev)	39.20 (9.386)	37.03 (13.338)	34.30 (13.483)	41.20 (12.660)	
Median	36.27	36.27	36.27	46.54	
Min, Max	26.0, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C6D1 CFB					
n	11	25	47	97	
LS Mean (StdErr) [2]	4.66 (3.232)	3.88 (1.939)	2.37 (1.509)	9.27 (1.077)	
95% CI [2]	-1.91, 11.24	-0.07, 7.82	-0.62, 5.35	7.14, 11.40	
Difference (95% CI) in CFB [2]		-0.78 (-8.16, 6.59)		6.90 (3.28, 10.52)	
p-value [3]		0.830		<0.001	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	37.85 (5.697)	37.09 (16.217)	37.74 (12.579)	40.30 (12.695)	
Median	36.27	36.27	36.27	46.54	
Min, Max	26.0, 46.5	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C7D1 CFB					
n	10	23	49	97	
LS Mean (StdErr) [2]	0.59 (3.575)	1.11 (2.152)	4.98 (1.468)	7.90 (1.059)	
95% CI [2]	-6.71, 7.89	-3.29, 5.51	2.07, 7.88	5.80, 9.99	
Difference (95% CI) in CFB [2]		0.52 (-7.66, 8.69)		2.92 (-0.60, 6.45)	
Hedges'G (95% CI) in CFB		0.05 (-0.72, 0.82)		0.28 (-0.06, 0.63)	
p-value [3]		0.898		0.103	
					0.473

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	12	27	55	108	
Mean (StdDev)	35.36 (8.945)	34.77 (9.562)	33.48 (10.736)	33.59 (9.677)	
Median	30.05	30.05	30.05	30.05	
Min, Max	19.4, 44.9	19.4, 55.5	19.4, 61.9	19.4, 55.5	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	39.68 (8.569)	36.03 (12.205)	35.24 (11.308)	35.74 (10.364)	
Median	44.92	30.05	30.05	30.05	
Min, Max	30.0, 55.5	19.4, 55.5	19.4, 55.5	19.4, 55.5	
C2D1 CFB					
n	12	26	53	106	
LS Mean (StdErr) [2]	4.65 (3.021)	0.40 (1.828)	1.50 (1.105)	2.49 (0.803)	
95% CI [2]	-1.48, 10.79	-3.31, 4.11	-0.68, 3.68	0.91, 4.08	
Difference (95% CI) in CFB [2]		-4.25 (-11.20, 2.70)		1.00 (-1.66, 3.65)	
p-value [3]		0.223		0.461	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	102	
Mean (StdDev)	38.69 (8.777)	34.29 (11.080)	34.17 (10.180)	38.21 (10.939)	
Median	44.92	30.05	30.05	44.92	
Min, Max	30.0, 55.5	19.4, 55.5	19.4, 55.5	19.4, 61.9	
C3D1 CFB					
n	12	26	51	99	
LS Mean (StdErr) [2]	4.91 (2.536)	0.04 (1.535)	0.52 (1.262)	5.28 (0.919)	
95% CI [2]	-0.24, 10.06	-3.08, 3.16	-1.97, 3.02	3.47, 7.10	
Difference (95% CI) in CFB [2]		-4.87 (-10.70, 0.96)		4.76 (1.73, 7.79)	
p-value [3]		0.099		0.002	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	36.58 (9.033)	34.47 (10.904)	35.83 (11.152)	38.22 (10.972)	
Median	30.05	30.05	30.05	44.92	
Min, Max	30.0, 55.5	19.4, 55.5	19.4, 61.9	19.4, 55.5	
C4D1 CFB					
n	10	24	46	101	
LS Mean (StdErr) [2]	0.89 (3.063)	-0.03 (1.822)	2.03 (1.378)	4.66 (0.955)	
95% CI [2]	-5.36, 7.13	-3.75, 3.68	-0.69, 4.76	2.78, 6.55	
Difference (95% CI) in CFB [2]		-0.92 (-7.85, 6.01)		2.63 (-0.62, 5.89)	
p-value [3]		0.788		0.112	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	99	
Mean (StdDev)	38.24 (8.931)	36.09 (11.923)	35.78 (10.428)	38.52 (10.490)	
Median	37.48	30.05	30.05	44.92	
Min, Max	30.0, 55.5	19.4, 55.5	19.4, 61.9	19.4, 55.5	
C5D1 CFB					
n	11	25	50	94	
LS Mean (StdErr) [2]	3.60 (2.800)	1.01 (1.703)	2.17 (1.353)	5.28 (1.010)	
95% CI [2]	-2.10, 9.30	-2.46, 4.47	-0.50, 4.85	3.28, 7.28	
Difference (95% CI) in CFB [2]		-2.59 (-8.89, 3.70)		3.11 (-0.18, 6.39)	
p-value [3]		0.408		0.064	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	41.43 (7.976)	37.68 (11.415)	34.74 (11.628)	39.02 (10.976)	
Median	44.92	44.92	30.05	44.92	
Min, Max	30.0, 55.5	19.4, 55.5	19.4, 61.9	19.4, 55.5	
C6D1 CFB					
n	11	26	48	97	
LS Mean (StdErr) [2]	5.23 (2.911)	2.40 (1.727)	0.83 (1.339)	5.28 (0.964)	
95% CI [2]	-0.68, 11.15	-1.11, 5.91	-1.82, 3.48	3.37, 7.18	
Difference (95% CI) in CFB [2]		-2.83 (-9.41, 3.74)		4.45 (1.23, 7.66)	
p-value [3]		0.388		0.007	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	40.01 (8.690)	36.76 (12.594)	35.77 (11.261)	39.56 (10.510)	
Median	44.92	30.05	30.05	44.92	
Min, Max	30.0, 55.5	19.4, 55.5	19.4, 55.5	19.4, 55.5	
C7D1 CFB					
n	10	24	49	97	
LS Mean (StdErr) [2]	3.76 (3.276)	1.15 (1.949)	1.51 (1.358)	5.89 (0.979)	
95% CI [2]	-2.93, 10.44	-2.82, 5.13	-1.17, 4.20	3.96, 7.83	
Difference (95% CI) in CFB [2]		-2.60 (-10.02, 4.81)		4.38 (1.12, 7.64)	
Hedges'G (95% CI) in CFB		-0.26 (-1.05, 0.49)		0.45 (0.11, 0.81)	
p-value [3]		0.479		0.009	
					0.078

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	12	27	55	108	
Mean (StdDev)	43.13 (8.823)	35.36 (7.062)	38.60 (8.797)	38.16 (8.590)	
Median	48.00	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 48.0	28.5, 57.8	28.5, 57.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	43.45 (10.340)	37.89 (9.167)	40.06 (8.489)	40.47 (9.588)	
Median	48.00	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 67.5	28.5, 57.8	
C2D1 CFB					
n	12	26	53	106	
LS Mean (StdErr) [2]	0.70 (2.829)	3.28 (1.712)	1.45 (1.061)	2.46 (0.771)	
95% CI [2]	-5.05, 6.44	-0.20, 6.76	-0.65, 3.54	0.93, 3.98	
Difference (95% CI) in CFB [2]		2.58 (-3.92, 9.09)		1.01 (-1.54, 3.56)	
p-value [3]		0.426		0.436	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	102	
Mean (StdDev)	42.80 (11.580)	38.62 (8.931)	41.25 (8.964)	41.40 (10.008)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 48.0	28.5, 67.5	28.5, 57.8	
C3D1 CFB					
n	12	26	51	99	
LS Mean (StdErr) [2]	0.99 (3.403)	3.93 (2.059)	2.89 (1.017)	3.31 (0.740)	
95% CI [2]	-5.92, 7.90	-0.25, 8.11	0.88, 4.90	1.84, 4.77	
Difference (95% CI) in CFB [2]		2.94 (-4.88, 10.77)		0.41 (-2.03, 2.85)	
p-value [3]		0.450		0.738	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	40.50 (8.116)	37.03 (10.093)	40.12 (8.780)	42.06 (10.076)	
Median	38.25	33.37	38.25	38.25	
Min, Max	28.5, 48.0	28.5, 57.8	28.5, 57.8	28.5, 57.8	
C4D1 CFB					
n	10	24	46	101	
LS Mean (StdErr) [2]	-1.98 (3.158)	2.43 (1.879)	2.54 (1.358)	3.80 (0.941)	
95% CI [2]	-8.42, 4.46	-1.40, 6.26	-0.14, 5.23	1.94, 5.66	
Difference (95% CI) in CFB [2]		4.41 (-2.74, 11.56)		1.26 (-1.95, 4.47)	
p-value [3]		0.218		0.439	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	99	
Mean (StdDev)	44.52 (9.834)	38.25 (9.150)	39.61 (9.032)	42.39 (10.057)	
Median	48.00	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 57.8	28.5, 67.5	
C5D1 CFB					
n	11	25	50	94	
LS Mean (StdErr) [2]	3.32 (2.971)	4.04 (1.808)	1.54 (1.329)	3.96 (0.992)	
95% CI [2]	-2.73, 9.36	0.36, 7.72	-1.09, 4.17	2.00, 5.92	
Difference (95% CI) in CFB [2]		0.72 (-5.96, 7.41)		2.42 (-0.80, 5.65)	
p-value [3]		0.827		0.140	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	43.13 (8.338)	38.61 (8.758)	38.25 (8.998)	43.70 (10.046)	
Median	48.00	38.25	38.25	48.00	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 57.8	28.5, 67.5	
C6D1 CFB					
n	11	26	48	97	
LS Mean (StdErr) [2]	1.78 (2.317)	4.25 (1.375)	0.65 (1.312)	5.23 (0.945)	
95% CI [2]	-2.93, 6.49	1.46, 7.05	-1.95, 3.24	3.36, 7.10	
Difference (95% CI) in CFB [2]		2.47 (-2.76, 7.71)		4.58 (1.43, 7.74)	
p-value [3]		0.344		0.005	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	46.50 (9.628)	39.81 (10.788)	40.24 (10.342)	42.65 (10.237)	
Median	48.00	38.25	38.25	38.25	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 67.5	28.5, 67.5	
C7D1 CFB					
n	10	24	49	97	
LS Mean (StdErr) [2]	4.69 (3.420)	4.62 (2.034)	2.26 (1.242)	3.94 (0.896)	
95% CI [2]	-2.28, 11.66	0.47, 8.76	-0.20, 4.71	2.17, 5.71	
Difference (95% CI) in CFB [2]		-0.07 (-7.81, 7.66)		1.68 (-1.30, 4.66)	
Hedges'G (95% CI) in CFB		-0.01 (-0.77, 0.76)		0.19 (-0.15, 0.54)	
p-value [3]		0.984		0.266	
					0.890

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	12	27	55	108	
Mean (StdDev)	37.11 (9.876)	36.29 (10.649)	37.01 (12.195)	38.03 (11.326)	
Median	36.29	36.29	36.29	36.29	
Min, Max	26.4, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	36.95 (10.239)	39.22 (10.935)	40.69 (11.007)	41.33 (11.454)	
Median	36.29	36.29	46.20	46.20	
Min, Max	16.5, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C2D1 CFB					
n	12	26	53	106	
LS Mean (StdErr) [2]	0.14 (2.801)	3.23 (1.695)	3.30 (1.413)	3.23 (1.027)	
95% CI [2]	-5.55, 5.83	-0.21, 6.67	0.51, 6.09	1.20, 5.26	
Difference (95% CI) in CFB [2]		3.09 (-3.36, 9.53)		-0.07 (-3.47, 3.33)	
p-value [3]		0.337		0.967	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	102	
Mean (StdDev)	40.25 (11.116)	39.72 (11.542)	41.05 (11.362)	41.15 (11.817)	
Median	36.29	36.29	36.29	46.20	
Min, Max	26.4, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C3D1 CFB					
n	12	26	51	99	
LS Mean (StdErr) [2]	3.10 (2.480)	4.31 (1.501)	4.48 (1.379)	2.92 (1.003)	
95% CI [2]	-1.93, 8.14	1.26, 7.36	1.75, 7.20	0.93, 4.90	
Difference (95% CI) in CFB [2]		1.21 (-4.50, 6.91)		-1.56 (-4.87, 1.75)	
p-value [3]		0.670		0.353	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	40.86 (11.880)	38.35 (11.315)	39.24 (10.922)	42.14 (12.350)	
Median	36.29	36.29	36.29	46.20	
Min, Max	16.5, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C4D1 CFB					
n	10	24	46	101	
LS Mean (StdErr) [2]	1.48 (3.107)	2.73 (1.848)	2.68 (1.582)	4.22 (1.096)	
95% CI [2]	-4.86, 7.82	-1.03, 6.50	-0.45, 5.81	2.05, 6.39	
Difference (95% CI) in CFB [2]		1.25 (-5.78, 8.28)		1.54 (-2.19, 5.28)	
p-value [3]		0.719		0.416	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	99	
Mean (StdDev)	41.24 (10.103)	40.48 (13.204)	39.26 (12.388)	43.80 (11.514)	
Median	36.29	36.29	36.29	46.20	
Min, Max	26.4, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C5D1 CFB					
n	11	25	50	94	
LS Mean (StdErr) [2]	4.17 (3.505)	5.26 (2.132)	2.10 (1.559)	5.74 (1.164)	
95% CI [2]	-2.96, 11.30	0.92, 9.60	-0.98, 5.18	3.44, 8.04	
Difference (95% CI) in CFB [2]		1.09 (-6.79, 8.97)		3.64 (-0.14, 7.42)	
p-value [3]		0.780		0.059	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	38.41 (8.849)	40.69 (11.773)	39.38 (12.297)	43.19 (12.065)	
Median	36.29	46.20	36.29	46.20	
Min, Max	26.4, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C6D1 CFB					
n	11	26	48	97	
LS Mean (StdErr) [2]	1.37 (3.027)	4.96 (1.796)	2.21 (1.651)	4.72 (1.188)	
95% CI [2]	-4.78, 7.52	1.31, 8.61	-1.05, 5.48	2.37, 7.07	
Difference (95% CI) in CFB [2]		3.59 (-3.24, 10.43)		2.50 (-1.47, 6.47)	
p-value [3]		0.293		0.215	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	41.62 (10.410)	40.65 (12.825)	40.33 (12.296)	43.28 (12.129)	
Median	36.29	46.20	36.29	46.20	
Min, Max	26.4, 56.1	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C7D1 CFB					
n	10	24	49	97	
LS Mean (StdErr) [2]	2.85 (3.494)	3.99 (2.078)	2.54 (1.624)	5.09 (1.171)	
95% CI [2]	-4.28, 9.97	-0.25, 8.23	-0.67, 5.75	2.78, 7.41	
Difference (95% CI) in CFB [2]		1.14 (-6.77, 9.04)		2.55 (-1.34, 6.45)	
Hedges'G (95% CI) in CFB		0.11 (-0.65, 0.88)		0.22 (-0.12, 0.57)	
p-value [3]		0.771		0.197	
					0.932

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	12	27	55	108	
Mean (StdDev)	36.51 (10.912)	33.96 (12.291)	37.67 (12.234)	39.27 (11.468)	
Median	33.75	33.75	33.75	39.27	
Min, Max	22.7, 55.8	11.7, 55.8	11.7, 55.8	11.7, 55.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	41.48 (11.763)	39.07 (11.504)	39.78 (11.258)	42.23 (11.670)	
Median	44.79	39.27	39.27	44.79	
Min, Max	22.7, 55.8	11.7, 55.8	17.2, 55.8	11.7, 55.8	
C2D1 CFB					
n	12	26	53	106	
LS Mean (StdErr) [2]	5.20 (3.587)	5.46 (2.171)	1.90 (1.199)	2.54 (0.871)	
95% CI [2]	-2.08, 12.48	1.05, 9.87	-0.46, 4.27	0.82, 4.26	
Difference (95% CI) in CFB [2]		0.26 (-7.99, 8.51)		0.64 (-2.25, 3.52)	
p-value [3]		0.950		0.663	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	102	
Mean (StdDev)	43.69 (14.178)	39.48 (12.632)	40.33 (11.874)	42.52 (11.633)	
Median	50.31	33.75	44.79	44.79	
Min, Max	11.7, 55.8	11.7, 55.8	11.7, 55.8	11.7, 55.8	
C3D1 CFB					
n	12	26	51	99	
LS Mean (StdErr) [2]	3.50 (3.931)	5.23 (2.379)	3.11 (1.245)	3.80 (0.906)	
95% CI [2]	-4.48, 11.48	0.40, 10.06	0.65, 5.57	2.01, 5.59	
Difference (95% CI) in CFB [2]		1.73 (-7.31, 10.77)		0.69 (-2.29, 3.68)	
p-value [3]		0.700		0.647	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	104	
Mean (StdDev)	44.37 (11.144)	36.05 (12.597)	38.21 (11.995)	44.21 (11.195)	
Median	44.79	33.75	33.75	44.79	
Min, Max	28.2, 55.8	17.2, 55.8	17.2, 55.8	11.7, 55.8	
C4D1 CFB					
n	10	24	46	100	
LS Mean (StdErr) [2]	7.50 (3.852)	2.40 (2.292)	1.65 (1.487)	5.34 (1.034)	
95% CI [2]	-0.36, 15.35	-2.27, 7.07	-1.30, 4.59	3.29, 7.38	
Difference (95% CI) in CFB [2]		-5.10 (-13.81, 3.62)		3.69 (0.17, 7.21)	
p-value [3]		0.242		0.040	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	99	
Mean (StdDev)	47.55 (9.620)	39.70 (10.578)	39.27 (12.214)	44.07 (11.112)	
Median	50.31	39.27	39.27	44.79	
Min, Max	28.2, 55.8	22.7, 55.8	11.7, 55.8	11.7, 55.8	
C5D1 CFB					
n	11	25	50	94	
LS Mean (StdErr) [2]	8.19 (3.818)	4.67 (2.323)	1.25 (1.490)	4.00 (1.112)	
95% CI [2]	0.42, 15.95	-0.06, 9.39	-1.70, 4.20	1.81, 6.20	
Difference (95% CI) in CFB [2]		-3.52 (-12.11, 5.07)		2.75 (-0.86, 6.37)	
p-value [3]		0.410		0.134	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	48	102	
Mean (StdDev)	46.76 (10.954)	37.84 (12.206)	39.50 (12.978)	43.71 (11.362)	
Median	50.31	33.75	39.27	44.79	
Min, Max	22.7, 55.8	11.7, 55.8	11.7, 55.8	11.7, 55.8	
C6D1 CFB					
n	11	26	48	97	
LS Mean (StdErr) [2]	8.82 (3.905)	3.69 (2.317)	1.65 (1.629)	3.57 (1.173)	
95% CI [2]	0.89, 16.76	-1.02, 8.40	-1.57, 4.87	1.25, 5.89	
Difference (95% CI) in CFB [2]		-5.13 (-13.95, 3.69)		1.92 (-2.00, 5.84)	
p-value [3]		0.245		0.334	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	43.09 (11.352)	36.62 (11.391)	39.72 (13.081)	44.14 (11.209)	
Median	44.79	33.75	39.27	44.79	
Min, Max	22.7, 55.8	11.7, 55.8	11.7, 55.8	11.7, 55.8	
C7D1 CFB					
n	10	24	49	97	
LS Mean (StdErr) [2]	2.08 (3.798)	2.55 (2.259)	1.49 (1.407)	4.55 (1.014)	
95% CI [2]	-5.66, 9.83	-2.06, 7.16	-1.29, 4.27	2.54, 6.55	
Difference (95% CI) in CFB [2]		0.47 (-8.13, 9.06)		3.05 (-0.32, 6.43)	
Hedges'G (95% CI) in CFB		0.04 (-0.72, 0.81)		0.31 (-0.04, 0.66)	
p-value [3]		0.913		0.076	
					0.587

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	12	27	55	108	
Mean (StdDev)	42.64 (8.796)	35.76 (9.566)	41.14 (9.949)	40.83 (10.109)	
Median	42.64	39.59	39.59	39.59	
Min, Max	33.5, 57.8	21.3, 57.8	21.3, 63.9	15.3, 63.9	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	43.65 (10.196)	40.04 (10.924)	41.85 (10.589)	42.14 (10.337)	
Median	45.68	39.59	39.59	39.59	
Min, Max	21.3, 57.8	15.3, 57.8	27.4, 63.9	15.3, 63.9	
C2D1 CFB					
n	12	26	53	106	
LS Mean (StdErr) [2]	-0.01 (2.311)	4.44 (1.399)	0.71 (0.971)	1.31 (0.706)	
95% CI [2]	-4.71, 4.68	1.60, 7.28	-1.21, 2.63	-0.08, 2.71	
Difference (95% CI) in CFB [2]		4.46 (-0.86, 9.77)		0.60 (-1.73, 2.94)	
p-value [3]		0.098		0.610	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	102	
Mean (StdDev)	44.46 (10.075)	40.30 (12.446)	42.52 (10.467)	44.42 (10.531)	
Median	45.68	39.59	39.59	45.68	
Min, Max	27.4, 57.8	15.3, 57.8	15.3, 63.9	21.3, 63.9	
C3D1 CFB					
n	12	26	51	99	
LS Mean (StdErr) [2]	-0.51 (2.242)	4.59 (1.357)	1.74 (1.212)	4.03 (0.882)	
95% CI [2]	-5.06, 4.04	1.83, 7.34	-0.66, 4.13	2.29, 5.77	
Difference (95% CI) in CFB [2]		5.10 (-0.06, 10.25)		2.30 (-0.61, 5.20)	
p-value [3]		0.053		0.121	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	24	47	105	
Mean (StdDev)	46.61 (7.793)	40.61 (11.009)	41.67 (10.169)	45.16 (10.708)	
Median	45.68	39.59	39.59	45.68	
Min, Max	33.5, 57.8	21.3, 57.8	21.3, 63.9	15.3, 63.9	
C4D1 CFB					
n	10	24	46	101	
LS Mean (StdErr) [2]	4.85 (2.359)	5.57 (1.403)	1.20 (1.332)	4.57 (0.922)	
95% CI [2]	0.04, 9.66	2.71, 8.43	-1.43, 3.83	2.75, 6.40	
Difference (95% CI) in CFB [2]		0.72 (-4.61, 6.06)		3.37 (0.23, 6.52)	
p-value [3]		0.784		0.036	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	99	
Mean (StdDev)	47.42 (8.412)	40.53 (9.532)	41.78 (11.315)	44.76 (10.441)	
Median	48.72	39.59	39.59	45.68	
Min, Max	33.5, 57.8	27.4, 57.8	21.3, 63.9	15.3, 63.9	
C5D1 CFB					
n	11	25	50	94	
LS Mean (StdErr) [2]	0.75 (2.381)	4.61 (1.449)	0.93 (1.322)	3.42 (0.987)	
95% CI [2]	-4.10, 5.59	1.66, 7.56	-1.68, 3.55	1.47, 5.37	
Difference (95% CI) in CFB [2]		3.86 (-1.50, 9.22)		2.48 (-0.72, 5.69)	
p-value [3]		0.152		0.128	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	47	102	
Mean (StdDev)	47.85 (8.129)	41.17 (11.139)	41.67 (10.090)	44.19 (10.569)	
Median	45.68	39.59	39.59	45.68	
Min, Max	33.5, 57.8	15.3, 57.8	27.4, 63.9	15.3, 63.9	
C6D1 CFB					
n	11	26	47	97	
LS Mean (StdErr) [2]	3.04 (2.792)	5.54 (1.656)	0.06 (1.300)	2.95 (0.927)	
95% CI [2]	-2.63, 8.72	2.17, 8.90	-2.51, 2.63	1.11, 4.78	
Difference (95% CI) in CFB [2]		2.49 (-3.81, 8.80)		2.88 (-0.23, 6.00)	
p-value [3]		0.427		0.070	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	46.61 (10.193)	41.05 (11.283)	42.08 (11.031)	44.72 (11.729)	
Median	45.68	39.59	39.59	45.68	
Min, Max	27.4, 63.9	15.3, 57.8	15.3, 63.9	15.3, 63.9	
C7D1 CFB					
n	10	24	49	97	
LS Mean (StdErr) [2]	0.75 (3.114)	4.29 (1.852)	0.94 (1.485)	3.88 (1.071)	
95% CI [2]	-5.60, 7.10	0.51, 8.07	-2.00, 3.88	1.76, 6.00	
Difference (95% CI) in CFB [2]		3.54 (-3.50, 10.59)		2.94 (-0.62, 6.50)	
Hedges'G (95% CI) in CFB		0.37 (-0.37, 1.17)		0.28 (-0.07, 0.63)	
p-value [3]		0.313		0.105	
					0.946

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	12	26	55	108	
Mean (StdDev)	35.00 (8.411)	34.62 (11.586)	33.87 (11.195)	33.64 (10.633)	
Median	35.35	32.38	31.33	33.38	
Min, Max	15.6, 45.0	19.6, 55.6	13.8, 60.4	10.5, 61.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	37.27 (9.374)	36.38 (13.578)	36.39 (11.409)	38.06 (11.729)	
Median	38.08	37.28	35.34	38.98	
Min, Max	16.5, 48.7	18.3, 57.0	16.9, 61.2	13.0, 58.5	
C2D1 CFB					
n	12	25	53	106	
LS Mean (StdErr) [2]	0.22 (2.157)	0.05 (1.322)	2.71 (0.936)	4.47 (0.680)	
95% CI [2]	-4.16, 4.61	-2.64, 2.73	0.86, 4.56	3.13, 5.82	
Difference (95% CI) in CFB [2]		-0.18 (-5.19, 4.84)		1.76 (-0.49, 4.01)	
p-value [3]		0.944		0.124	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	102	
Mean (StdDev)	37.30 (10.168)	38.08 (12.378)	35.84 (10.292)	38.95 (12.136)	
Median	38.08	39.53	34.67	39.46	
Min, Max	15.1, 53.8	15.3, 59.5	17.4, 62.6	13.3, 61.4	
C3D1 CFB					
n	12	25	51	99	
LS Mean (StdErr) [2]	1.77 (2.191)	3.04 (1.343)	2.08 (0.964)	5.30 (0.701)	
95% CI [2]	-2.69, 6.22	0.31, 5.77	0.17, 3.98	3.92, 6.69	
Difference (95% CI) in CFB [2]		1.27 (-3.83, 6.37)		3.22 (0.91, 5.53)	
p-value [3]		0.616		0.007	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	22	47	104	
Mean (StdDev)	35.42 (9.094)	38.24 (11.407)	36.98 (11.046)	39.16 (11.721)	
Median	38.71	39.33	36.24	40.80	
Min, Max	10.8, 44.5	17.6, 57.1	19.6, 61.5	12.8, 59.8	
C4D1 CFB					
n	10	21	46	100	
LS Mean (StdErr) [2]	-1.56 (2.524)	3.28 (1.583)	3.53 (1.098)	5.30 (0.763)	
95% CI [2]	-6.73, 3.61	0.03, 6.52	1.36, 5.70	3.79, 6.81	
Difference (95% CI) in CFB [2]		4.84 (-0.98, 10.65)		1.78 (-0.82, 4.37)	
p-value [3]		0.100		0.179	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	99	
Mean (StdDev)	36.91 (8.378)	38.96 (14.394)	36.57 (11.914)	38.88 (11.529)	
Median	38.96	39.29	36.66	38.75	
Min, Max	15.9, 48.9	13.3, 64.3	13.5, 60.1	13.0, 62.4	
C5D1 CFB					
n	11	24	50	94	
LS Mean (StdErr) [2]	0.71 (2.140)	2.58 (1.316)	2.84 (1.086)	5.96 (0.811)	
95% CI [2]	-3.65, 5.07	-0.10, 5.26	0.69, 4.98	4.35, 7.56	
Difference (95% CI) in CFB [2]		1.86 (-3.00, 6.72)		3.12 (0.48, 5.75)	
p-value [3]		0.441		0.021	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	47	102	
Mean (StdDev)	37.38 (7.607)	38.51 (13.005)	35.19 (11.961)	40.96 (11.580)	
Median	40.31	37.31	32.15	41.78	
Min, Max	16.9, 44.3	18.0, 59.1	16.4, 58.8	17.3, 61.0	
C6D1 CFB					
n	11	25	47	97	
LS Mean (StdErr) [2]	0.53 (1.950)	2.80 (1.170)	1.83 (1.162)	7.44 (0.829)	
95% CI [2]	-3.44, 4.50	0.42, 5.18	-0.46, 4.13	5.80, 9.08	
Difference (95% CI) in CFB [2]		2.27 (-2.18, 6.72)		5.61 (2.82, 8.40)	
p-value [3]		0.308		<0.001	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	38.98 (3.351)	39.11 (14.427)	37.12 (12.205)	40.06 (11.726)	
Median	39.35	40.18	36.03	39.50	
Min, Max	33.4, 44.7	12.5, 57.4	14.5, 63.2	13.6, 63.1	
C7D1 CFB					
n	10	23	49	97	
LS Mean (StdErr) [2]	0.38 (2.436)	1.78 (1.467)	3.00 (1.155)	6.00 (0.832)	
95% CI [2]	-4.59, 5.36	-1.21, 4.78	0.72, 5.29	4.35, 7.64	
Difference (95% CI) in CFB [2]		1.40 (-4.17, 6.97)		2.99 (0.22, 5.76)	
Hedges'G (95% CI) in CFB		0.19 (-0.57, 0.98)		0.36 (0.02, 0.72)	
p-value [3]		0.612		0.034	
					0.473

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
Baseline					
n	12	26	55	108	
Mean (StdDev)	41.85 (10.157)	36.78 (9.231)	40.80 (10.853)	41.52 (10.631)	
Median	38.92	36.02	39.84	42.15	
Min, Max	28.0, 58.2	21.2, 61.2	19.2, 63.9	13.2, 64.0	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C2D1					
n	15	27	54	110	
Mean (StdDev)	43.41 (9.953)	40.58 (11.127)	42.34 (11.243)	43.03 (10.198)	
Median	44.76	38.11	42.36	42.93	
Min, Max	26.3, 60.7	19.0, 62.2	19.9, 64.4	19.6, 64.8	
C2D1 CFB					
n	12	25	53	106	
LS Mean (StdErr) [2]	2.63 (2.469)	4.96 (1.513)	1.24 (1.070)	1.41 (0.777)	
95% CI [2]	-2.39, 7.65	1.88, 8.03	-0.87, 3.36	-0.12, 2.95	
Difference (95% CI) in CFB [2]		2.33 (-3.42, 8.07)		0.17 (-2.41, 2.74)	
p-value [3]		0.416		0.897	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C3D1					
n	15	26	52	102	
Mean (StdDev)	45.24 (10.859)	40.47 (12.418)	43.39 (10.889)	44.08 (9.977)	
Median	49.62	40.91	43.57	45.89	
Min, Max	23.4, 59.9	13.8, 66.0	11.2, 63.3	17.7, 60.6	
C3D1 CFB					
n	12	25	51	99	
LS Mean (StdErr) [2]	1.95 (2.700)	4.46 (1.654)	2.96 (1.109)	2.97 (0.807)	
95% CI [2]	-3.53, 7.44	1.10, 7.83	0.77, 5.16	1.38, 4.57	
Difference (95% CI) in CFB [2]		2.51 (-3.77, 8.79)		0.01 (-2.65, 2.67)	
p-value [3]		0.422		0.995	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C4D1					
n	13	22	47	104	
Mean (StdDev)	46.34 (8.968)	38.88 (10.920)	41.23 (10.162)	45.45 (10.431)	
Median	43.70	39.88	40.82	46.14	
Min, Max	34.3, 58.4	13.7, 60.2	22.0, 59.7	16.0, 63.9	
C4D1 CFB					
n	10	21	46	100	
LS Mean (StdErr) [2]	4.42 (2.775)	3.17 (1.740)	1.22 (1.350)	4.17 (0.938)	
95% CI [2]	-1.27, 10.10	-0.40, 6.73	-1.45, 3.88	2.31, 6.02	
Difference (95% CI) in CFB [2]		-1.25 (-7.64, 5.14)		2.95 (-0.24, 6.14)	
p-value [3]		0.692		0.070	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C5D1					
n	14	26	50	99	
Mean (StdDev)	48.60 (8.917)	40.41 (10.689)	41.62 (11.920)	45.74 (10.222)	
Median	48.25	39.78	41.30	47.19	
Min, Max	32.4, 61.5	22.2, 64.4	14.1, 61.6	19.5, 62.5	
C5D1 CFB					
n	11	24	50	94	
LS Mean (StdErr) [2]	5.22 (2.878)	4.80 (1.770)	0.80 (1.393)	3.40 (1.040)	
95% CI [2]	-0.64, 11.09	1.20, 8.41	-1.95, 3.56	1.34, 5.45	
Difference (95% CI) in CFB [2]		-0.42 (-6.96, 6.12)		2.60 (-0.78, 5.97)	
p-value [3]		0.896		0.131	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C6D1					
n	14	27	47	102	
Mean (StdDev)	47.51 (8.962)	40.41 (11.609)	42.13 (10.755)	44.78 (10.533)	
Median	47.14	38.16	39.67	46.40	
Min, Max	31.1, 61.2	16.6, 61.4	24.1, 61.4	12.1, 61.5	
C6D1 CFB					
n	11	25	47	97	
LS Mean (StdErr) [2]	5.70 (2.773)	4.64 (1.664)	0.94 (1.404)	2.54 (1.001)	
95% CI [2]	0.06, 11.34	1.25, 8.02	-1.83, 3.72	0.56, 4.52	
Difference (95% CI) in CFB [2]		-1.06 (-7.39, 5.26)		1.59 (-1.77, 4.96)	
p-value [3]		0.735		0.351	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.6a
Change from Baseline of SF-12 by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Baseline serum tryptase level = <20 ng/mL		Baseline serum tryptase level = >=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	Test of Interaction p-value [1]
C7D1					
n	13	25	49	102	
Mean (StdDev)	46.50 (11.496)	39.90 (11.103)	42.24 (11.427)	45.32 (11.191)	
Median	46.80	43.03	42.82	46.12	
Min, Max	26.3, 64.6	19.6, 63.3	12.1, 64.9	12.0, 62.7	
C7D1 CFB					
n	10	23	49	97	
LS Mean (StdErr) [2]	3.18 (3.308)	4.08 (1.992)	1.22 (1.342)	3.69 (0.967)	
95% CI [2]	-3.58, 9.93	0.01, 8.14	-1.44, 3.87	1.78, 5.60	
Difference (95% CI) in CFB [2]		0.90 (-6.67, 8.46)		2.47 (-0.75, 5.69)	
Hedges'G (95% CI) in CFB		0.09 (-0.68, 0.87)		0.26 (-0.08, 0.61)	
p-value [3]		0.810		0.131	
					0.821

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-tryp-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	63	125	4	10	
Mean (StdDev)	38.88 (11.968)	38.14 (11.429)	24.96 (4.207)	28.75 (8.913)	
Median	39.69	39.69	22.86	22.86	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 31.3	22.9, 48.1	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	41.24 (10.715)	41.33 (11.713)	24.96 (4.207)	31.27 (12.621)	
Median	39.69	39.69	22.86	22.86	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 31.3	22.9, 56.5	
C2D1 CFB					
n	61	123	4	9	
LS Mean (StdErr) [2]	1.55 (1.051)	2.32 (0.795)	7.87 (2.658)	7.50 (2.024)	
95% CI [2]	-0.53, 3.62	0.76, 3.89	1.85, 13.88	2.92, 12.08	
Difference (95% CI) in CFB [2]		0.78 (-1.51, 3.06)		-0.37 (-5.40, 4.66)	
p-value [3]		0.503		0.873	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	119	4	9	
Mean (StdDev)	40.62 (10.037)	41.95 (11.833)	24.96 (4.207)	29.40 (9.196)	
Median	39.69	39.69	22.86	22.86	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 31.3	22.9, 48.1	
C3D1 CFB					
n	59	116	4	9	
LS Mean (StdErr) [2]	1.77 (1.132)	3.80 (0.846)	-0.55 (2.658)	-0.91 (2.024)	
95% CI [2]	-0.47, 4.00	2.13, 5.47	-6.56, 5.46	-5.49, 3.66	
Difference (95% CI) in CFB [2]		2.03 (-0.44, 4.50)		-0.37 (-5.40, 4.66)	
p-value [3]		0.106		0.873	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	40.74 (10.651)	42.37 (11.274)	27.06 (4.858)	30.43 (10.826)	
Median	39.69	39.69	27.06	22.86	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 31.3	22.9, 48.1	
C4D1 CFB					
n	52	115	4	10	
LS Mean (StdErr) [2]	2.84 (1.289)	4.63 (0.942)	4.99 (4.978)	2.96 (3.812)	
95% CI [2]	0.30, 5.39	2.77, 6.49	-6.11, 16.08	-5.53, 11.45	
Difference (95% CI) in CFB [2]		1.79 (-0.97, 4.54)		-2.03 (-11.24, 7.19)	
p-value [3]		0.202		0.635	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	115	4	10	
Mean (StdDev)	41.37 (11.778)	42.76 (11.329)	24.96 (4.207)	29.59 (10.343)	
Median	39.69	39.69	22.86	22.86	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 31.3	22.9, 48.1	
C5D1 CFB					
n	57	109	4	10	
LS Mean (StdErr) [2]	1.97 (1.271)	4.63 (0.965)	3.74 (3.734)	3.27 (2.859)	
95% CI [2]	-0.54, 4.48	2.72, 6.53	-4.58, 12.06	-3.10, 9.64	
Difference (95% CI) in CFB [2]		2.66 (-0.11, 5.42)		-0.47 (-7.38, 6.44)	
p-value [3]		0.060		0.883	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	40.12 (11.192)	43.72 (11.739)	27.06 (4.858)	28.75 (8.913)	
Median	39.69	48.10	27.06	22.86	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 31.3	22.9, 48.1	
C6D1 CFB					
n	55	113	4	10	
LS Mean (StdErr) [2]	0.71 (1.258)	5.12 (0.929)	1.87 (3.184)	-0.47 (2.438)	
95% CI [2]	-1.77, 3.19	3.28, 6.95	-5.22, 8.96	-5.90, 4.96	
Difference (95% CI) in CFB [2]		4.41 (1.67, 7.15)		-2.34 (-8.23, 3.55)	
p-value [3]		0.002		0.398	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	40.99 (10.897)	43.21 (11.912)	24.96 (4.207)	29.59 (10.343)	
Median	39.69	39.69	22.86	22.86	
Min, Max	22.9, 56.5	22.9, 56.5	22.9, 31.3	22.9, 48.1	
C7D1 CFB					
n	55	111	4	10	
LS Mean (StdErr) [2]	0.54 (1.431)	3.94 (1.063)	4.21 (3.900)	4.21 (2.986)	
95% CI [2]	-2.28, 3.37	1.85, 6.04	-4.48, 12.90	-2.45, 10.86	
Difference (95% CI) in CFB [2]		3.40 (0.33, 6.47)		0.00 (-7.22, 7.22)	
Hedges'G (95% CI) in CFB		0.31 (-0.02, 0.64)		NE	
p-value [3]		0.030		>0.999	
					0.577

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	63	125	4	10	
Mean (StdDev)	35.16 (7.558)	35.23 (8.692)	25.54 (5.184)	29.13 (6.278)	
Median	34.51	34.51	25.54	27.78	
Min, Max	21.0, 52.5	21.0, 57.0	21.0, 30.0	21.0, 39.0	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	36.93 (9.359)	37.99 (10.160)	27.78 (2.592)	32.52 (8.128)	
Median	39.00	39.00	27.78	30.03	
Min, Max	21.0, 57.0	21.0, 57.0	25.5, 30.0	21.0, 48.0	
C2D1 CFB					
n	61	123	4	9	
LS Mean (StdErr) [2]	0.79 (1.017)	1.70 (0.769)	5.27 (3.179)	6.54 (2.421)	
95% CI [2]	-1.22, 2.79	0.18, 3.21	-1.92, 12.46	1.06, 12.02	
Difference (95% CI) in CFB [2]		0.91 (-1.30, 3.12)		1.27 (-4.75, 7.29)	
p-value [3]		0.418		0.645	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	119	4	9	
Mean (StdDev)	37.29 (9.757)	39.65 (10.295)	28.90 (2.245)	33.52 (8.024)	
Median	39.00	39.00	30.03	34.51	
Min, Max	21.0, 57.0	21.0, 57.0	25.5, 30.0	21.0, 48.0	
C3D1 CFB					
n	59	116	4	9	
LS Mean (StdErr) [2]	1.50 (1.128)	4.02 (0.843)	5.47 (2.848)	6.49 (2.169)	
95% CI [2]	-0.73, 3.73	2.36, 5.69	-0.98, 11.91	1.58, 11.40	
Difference (95% CI) in CFB [2]		2.52 (0.07, 4.98)		1.02 (-4.36, 6.41)	
p-value [3]		0.044		0.677	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	117	4	10	
Mean (StdDev)	37.72 (9.862)	40.39 (10.218)	25.54 (3.666)	34.51 (9.698)	
Median	39.00	39.00	25.54	34.51	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 30.0	21.0, 48.0	
C4D1 CFB					
n	52	113	4	10	
LS Mean (StdErr) [2]	2.52 (1.203)	4.67 (0.888)	1.16 (5.221)	5.32 (3.997)	
95% CI [2]	0.15, 4.90	2.92, 6.43	-10.47, 12.80	-3.59, 14.23	
Difference (95% CI) in CFB [2]		2.15 (-0.43, 4.73)		4.16 (-5.50, 13.82)	
p-value [3]		0.101		0.360	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	115	4	10	
Mean (StdDev)	37.96 (9.143)	40.06 (10.079)	25.54 (3.666)	34.51 (8.196)	
Median	39.00	39.00	25.54	34.51	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 30.0	21.0, 43.5	
C5D1 CFB					
n	57	109	4	10	
LS Mean (StdErr) [2]	2.36 (1.157)	4.65 (0.879)	-0.17 (4.530)	5.65 (3.469)	
95% CI [2]	0.07, 4.64	2.91, 6.38	-10.26, 9.93	-2.08, 13.38	
Difference (95% CI) in CFB [2]		2.29 (-0.23, 4.81)		5.82 (-2.56, 14.20)	
p-value [3]		0.074		0.153	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	36.84 (9.779)	41.61 (10.182)	25.54 (3.666)	31.37 (4.756)	
Median	34.51	43.49	25.54	30.03	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 30.0	25.5, 39.0	
C6D1 CFB					
n	55	113	4	10	
LS Mean (StdErr) [2]	1.08 (1.263)	5.59 (0.933)	-1.16 (2.976)	1.41 (2.279)	
95% CI [2]	-1.41, 3.57	3.75, 7.43	-7.80, 5.47	-3.66, 6.49	
Difference (95% CI) in CFB [2]		4.51 (1.76, 7.26)		2.58 (-2.93, 8.08)	
p-value [3]		0.001		0.322	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	39.00 (9.950)	41.11 (10.669)	23.29 (4.489)	33.62 (9.176)	
Median	39.00	39.00	21.05	30.03	
Min, Max	21.0, 57.0	21.0, 57.0	21.0, 30.0	21.0, 52.5	
C7D1 CFB					
n	55	111	4	10	
LS Mean (StdErr) [2]	2.63 (1.330)	4.65 (0.988)	3.16 (4.838)	9.31 (3.705)	
95% CI [2]	0.01, 5.26	2.69, 6.60	-7.62, 13.94	1.06, 17.57	
Difference (95% CI) in CFB [2]		2.01 (-0.84, 4.87)		6.15 (-2.80, 15.11)	
Hedges'G (95% CI) in CFB		0.20 (-0.13, 0.52)		0.51 (-0.69, 1.93)	
p-value [3]		0.166		0.157	
					0.367

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	63	124	4	10	
Mean (StdDev)	33.17 (10.698)	32.87 (11.620)	20.86 (5.930)	23.94 (8.101)	
Median	36.27	31.13	20.86	26.00	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 26.0	15.7, 36.3	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	36.11 (11.410)	39.24 (12.439)	31.13 (10.270)	28.28 (9.981)	
Median	36.27	36.27	36.27	26.00	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 36.3	15.7, 46.5	
C2D1 CFB					
n	61	122	4	9	
LS Mean (StdErr) [2]	1.19 (1.389)	4.92 (1.060)	18.08 (7.330)	9.60 (5.582)	
95% CI [2]	-1.55, 3.93	2.83, 7.01	1.50, 34.67	-3.03, 22.23	
Difference (95% CI) in CFB [2]		3.73 (0.71, 6.75)		-8.48 (-22.36, 5.39)	
p-value [3]		0.016		0.200	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	119	4	9	
Mean (StdDev)	37.41 (11.085)	40.58 (11.618)	26.00 (8.386)	27.14 (10.826)	
Median	36.27	46.54	26.00	26.00	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 36.3	15.7, 46.5	
C3D1 CFB					
n	59	115	4	9	
LS Mean (StdErr) [2]	3.81 (1.351)	7.78 (1.018)	13.84 (4.527)	9.38 (3.448)	
95% CI [2]	1.14, 6.47	5.77, 9.79	3.60, 24.08	1.58, 17.18	
Difference (95% CI) in CFB [2]		3.97 (1.03, 6.92)		-4.47 (-13.03, 4.10)	
p-value [3]		0.009		0.269	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	118	4	10	
Mean (StdDev)	36.64 (10.898)	40.45 (12.177)	31.13 (5.930)	23.94 (8.101)	
Median	36.27	46.54	31.13	26.00	
Min, Max	15.7, 56.8	15.7, 56.8	26.0, 36.3	15.7, 36.3	
C4D1 CFB					
n	52	113	4	10	
LS Mean (StdErr) [2]	2.20 (1.558)	6.61 (1.165)	15.03 (4.738)	2.66 (3.628)	
95% CI [2]	-0.88, 5.28	4.31, 8.91	4.47, 25.58	-5.42, 10.75	
Difference (95% CI) in CFB [2]		4.41 (1.08, 7.73)		-12.36 (-21.13, -3.60)	
p-value [3]		0.010		0.010	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	115	4	10	
Mean (StdDev)	36.78 (12.023)	40.29 (12.739)	26.00 (8.386)	27.03 (10.213)	
Median	36.27	46.54	26.00	26.00	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 36.3	15.7, 46.5	
C5D1 CFB					
n	57	108	4	10	
LS Mean (StdErr) [2]	2.10 (1.557)	6.61 (1.193)	8.75 (4.997)	5.52 (3.826)	
95% CI [2]	-0.98, 5.17	4.25, 8.96	-2.38, 19.88	-3.01, 14.04	
Difference (95% CI) in CFB [2]		4.51 (1.12, 7.90)		-3.23 (-12.48, 6.01)	
p-value [3]		0.009		0.454	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	57	119	4	10	
Mean (StdDev)	36.63 (12.270)	41.27 (12.462)	18.30 (5.135)	29.08 (12.855)	
Median	36.27	46.54	15.73	26.00	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 26.0	15.7, 46.5	
C6D1 CFB					
n	54	112	4	10	
LS Mean (StdErr) [2]	1.93 (1.542)	7.31 (1.144)	0.95 (6.077)	8.75 (4.653)	
95% CI [2]	-1.11, 4.97	5.05, 9.57	-12.59, 14.49	-1.62, 19.12	
Difference (95% CI) in CFB [2]		5.38 (2.02, 8.74)		7.80 (-3.45, 19.04)	
p-value [3]		0.002		0.153	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	38.57 (11.225)	40.75 (13.240)	26.00 (8.386)	27.03 (8.993)	
Median	36.27	46.54	26.00	26.00	
Min, Max	15.7, 56.8	15.7, 56.8	15.7, 36.3	15.7, 46.5	
C7D1 CFB					
n	55	110	4	10	
LS Mean (StdErr) [2]	2.31 (1.573)	5.14 (1.180)	8.18 (4.534)	4.37 (3.472)	
95% CI [2]	-0.80, 5.42	2.81, 7.47	-1.93, 18.28	-3.36, 12.11	
Difference (95% CI) in CFB [2]		2.83 (-0.55, 6.21)		-3.80 (-12.19, 4.59)	
Hedges'G (95% CI) in CFB		0.23 (-0.09, 0.56)		-0.34 (-1.71, 0.89)	
p-value [3]		0.100		0.336	
					0.408

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	63	125	4	10	
Mean (StdDev)	34.56 (10.214)	34.26 (9.661)	22.08 (5.311)	28.35 (7.680)	
Median	30.05	30.05	19.42	30.05	
Min, Max	19.4, 61.9	19.4, 55.5	19.4, 30.0	19.4, 44.9	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	36.91 (10.727)	36.17 (10.663)	24.73 (6.133)	30.52 (10.450)	
Median	30.05	30.05	24.73	30.05	
Min, Max	19.4, 55.5	19.4, 55.5	19.4, 30.0	19.4, 55.5	
C2D1 CFB					
n	61	123	4	9	
LS Mean (StdErr) [2]	1.65 (1.168)	1.61 (0.884)	13.44 (4.046)	11.25 (3.081)	
95% CI [2]	-0.66, 3.95	-0.13, 3.35	4.29, 22.59	4.28, 18.22	
Difference (95% CI) in CFB [2]		-0.04 (-2.57, 2.50)		-2.19 (-9.85, 5.46)	
p-value [3]		0.977		0.533	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	119	4	9	
Mean (StdDev)	35.85 (9.856)	37.78 (11.056)	24.73 (6.133)	32.64 (10.177)	
Median	30.05	44.92	24.73	30.05	
Min, Max	19.4, 55.5	19.4, 61.9	19.4, 30.0	19.4, 44.9	
C3D1 CFB					
n	59	116	4	9	
LS Mean (StdErr) [2]	0.34 (1.287)	3.25 (0.961)	6.24 (6.053)	7.74 (4.610)	
95% CI [2]	-2.20, 2.88	1.36, 5.15	-7.46, 19.93	-2.69, 18.16	
Difference (95% CI) in CFB [2]		2.92 (0.11, 5.72)		1.50 (-9.95, 12.96)	
p-value [3]		0.042		0.774	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	36.80 (10.488)	37.79 (10.951)	24.73 (6.133)	34.29 (11.850)	
Median	30.05	44.92	24.73	37.48	
Min, Max	19.4, 61.9	19.4, 55.5	19.4, 30.0	19.4, 44.9	
C4D1 CFB					
n	52	115	4	10	
LS Mean (StdErr) [2]	0.99 (1.413)	2.62 (1.032)	7.32 (7.542)	9.32 (5.775)	
95% CI [2]	-1.80, 3.78	0.59, 4.66	-9.49, 24.12	-3.54, 22.19	
Difference (95% CI) in CFB [2]		1.63 (-1.39, 4.65)		2.01 (-11.95, 15.96)	
p-value [3]		0.288		0.755	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	115	4	10	
Mean (StdDev)	36.91 (10.090)	38.47 (10.686)	27.39 (5.311)	32.81 (11.289)	
Median	30.05	44.92	30.05	30.05	
Min, Max	19.4, 61.9	19.4, 55.5	19.4, 30.0	19.4, 44.9	
C5D1 CFB					
n	57	109	4	10	
LS Mean (StdErr) [2]	1.68 (1.361)	3.74 (1.033)	11.37 (8.772)	9.64 (6.716)	
95% CI [2]	-1.01, 4.37	1.70, 5.78	-8.17, 30.92	-5.32, 24.60	
Difference (95% CI) in CFB [2]		2.05 (-0.91, 5.02)		-1.73 (-17.96, 14.50)	
p-value [3]		0.173		0.817	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	37.22 (10.861)	39.40 (10.996)	22.08 (5.311)	30.90 (8.569)	
Median	37.48	44.92	19.42	30.05	
Min, Max	19.4, 61.9	19.4, 55.5	19.4, 30.0	19.4, 44.9	
C6D1 CFB					
n	55	113	4	10	
LS Mean (StdErr) [2]	1.60 (1.365)	4.65 (1.008)	-0.83 (7.748)	2.60 (5.932)	
95% CI [2]	-1.10, 4.29	2.66, 6.64	-18.09, 16.44	-10.62, 15.82	
Difference (95% CI) in CFB [2]		3.05 (0.07, 6.02)		3.42 (-10.91, 17.76)	
p-value [3]		0.045		0.606	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	37.66 (10.416)	39.49 (11.034)	22.08 (5.311)	33.44 (8.569)	
Median	37.48	44.92	19.42	30.05	
Min, Max	19.4, 55.5	19.4, 55.5	19.4, 30.0	19.4, 44.9	
C7D1 CFB					
n	55	111	4	10	
LS Mean (StdErr) [2]	0.99 (1.421)	4.01 (1.055)	5.00 (8.245)	8.58 (6.312)	
95% CI [2]	-1.82, 3.79	1.92, 6.09	-13.37, 23.37	-5.49, 22.64	
Difference (95% CI) in CFB [2]		3.02 (-0.03, 6.07)		3.58 (-11.68, 18.84)	
Hedges'G (95% CI) in CFB		0.27 (-0.05, 0.61)		0.17 (-1.08, 1.50)	
p-value [3]		0.052		0.612	
					0.716

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	63	125	4	10	
Mean (StdDev)	39.80 (8.968)	37.86 (8.347)	33.37 (5.631)	34.35 (8.225)	
Median	38.25	38.25	33.37	28.50	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 38.2	28.5, 48.0	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	41.25 (8.947)	40.23 (9.588)	33.37 (5.631)	36.08 (8.128)	
Median	38.25	38.25	33.37	38.25	
Min, Max	28.5, 67.5	28.5, 57.8	28.5, 38.2	28.5, 48.0	
C2D1 CFB					
n	61	123	4	9	
LS Mean (StdErr) [2]	1.32 (1.149)	2.75 (0.870)	-0.85 (2.179)	0.21 (1.659)	
95% CI [2]	-0.95, 3.59	1.03, 4.46	-5.78, 4.08	-3.54, 3.97	
Difference (95% CI) in CFB [2]		1.43 (-1.07, 3.93)		1.06 (-3.06, 5.18)	
p-value [3]		0.261		0.575	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	119	4	9	
Mean (StdDev)	41.81 (9.643)	41.28 (9.897)	38.25 (7.964)	35.00 (6.897)	
Median	38.25	38.25	38.25	38.25	
Min, Max	28.5, 67.5	28.5, 57.8	28.5, 48.0	28.5, 48.0	
C3D1 CFB					
n	59	116	4	9	
LS Mean (StdErr) [2]	2.05 (1.168)	3.51 (0.873)	5.51 (3.903)	1.06 (2.973)	
95% CI [2]	-0.26, 4.35	1.79, 5.24	-3.32, 14.34	-5.66, 7.79	
Difference (95% CI) in CFB [2]		1.47 (-1.08, 4.01)		-4.45 (-11.84, 2.94)	
p-value [3]		0.257		0.206	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	40.34 (8.667)	41.53 (10.181)	38.25 (7.964)	36.30 (10.074)	
Median	38.25	38.25	38.25	33.37	
Min, Max	28.5, 57.8	28.5, 57.8	28.5, 48.0	28.5, 57.8	
C4D1 CFB					
n	52	115	4	10	
LS Mean (StdErr) [2]	0.67 (1.382)	2.87 (1.009)	9.57 (8.379)	6.14 (6.415)	
95% CI [2]	-2.06, 3.39	0.88, 4.87	-9.10, 28.24	-8.15, 20.44	
Difference (95% CI) in CFB [2]		2.21 (-0.75, 5.16)		-3.43 (-18.94, 12.07)	
p-value [3]		0.142		0.633	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	115	4	10	
Mean (StdDev)	41.34 (9.243)	41.90 (10.046)	30.93 (4.877)	37.27 (8.540)	
Median	38.25	38.25	28.50	38.25	
Min, Max	28.5, 57.8	28.5, 67.5	28.5, 38.2	28.5, 57.8	
C5D1 CFB					
n	57	109	4	10	
LS Mean (StdErr) [2]	1.81 (1.394)	3.89 (1.059)	1.26 (4.685)	5.78 (3.587)	
95% CI [2]	-0.94, 4.57	1.80, 5.98	-9.17, 11.70	-2.21, 13.77	
Difference (95% CI) in CFB [2]		2.08 (-0.96, 5.12)		4.52 (-4.15, 13.18)	
p-value [3]		0.178		0.273	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	39.93 (8.976)	43.09 (9.908)	30.93 (4.877)	37.27 (9.700)	
Median	38.25	48.00	28.50	38.25	
Min, Max	28.5, 57.8	28.5, 67.5	28.5, 38.2	28.5, 57.8	
C6D1 CFB					
n	55	113	4	10	
LS Mean (StdErr) [2]	0.40 (1.305)	4.73 (0.964)	1.81 (5.571)	6.86 (4.265)	
95% CI [2]	-2.18, 2.97	2.83, 6.63	-10.61, 14.22	-2.64, 16.37	
Difference (95% CI) in CFB [2]		4.33 (1.49, 7.18)		5.06 (-5.25, 15.37)	
p-value [3]		0.003		0.300	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	42.12 (10.326)	42.25 (10.495)	33.37 (9.754)	40.20 (8.963)	
Median	38.25	38.25	28.50	38.25	
Min, Max	28.5, 67.5	28.5, 67.5	28.5, 48.0	28.5, 57.8	
C7D1 CFB					
n	55	111	4	10	
LS Mean (StdErr) [2]	2.70 (1.363)	3.93 (1.012)	1.81 (5.571)	6.86 (4.265)	
95% CI [2]	0.01, 5.39	1.93, 5.93	-10.61, 14.22	-2.64, 16.37	
Difference (95% CI) in CFB [2]		1.23 (-1.70, 4.16)		5.06 (-5.25, 15.37)	
Hedges'G (95% CI) in CFB		0.12 (-0.21, 0.44)		0.37 (-0.86, 1.74)	
p-value [3]		0.408		0.300	
					0.400

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	63	125	4	10	
Mean (StdDev)	38.17 (11.100)	38.03 (11.053)	18.94 (4.957)	33.31 (12.409)	
Median	36.29	36.29	16.46	36.29	
Min, Max	16.5, 56.1	16.5, 56.1	16.5, 26.4	16.5, 56.1	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	40.25 (11.057)	41.17 (11.334)	33.81 (4.957)	37.39 (11.566)	
Median	46.20	46.20	36.29	36.29	
Min, Max	16.5, 56.1	16.5, 56.1	26.4, 36.3	16.5, 56.1	
C2D1 CFB					
n	61	123	4	9	
LS Mean (StdErr) [2]	1.27 (1.409)	2.88 (1.066)	12.28 (7.076)	0.65 (5.389)	
95% CI [2]	-1.52, 4.05	0.77, 4.98	-3.72, 28.29	-11.54, 12.84	
Difference (95% CI) in CFB [2]		1.61 (-1.45, 4.68)		-11.64 (-25.03, 1.75)	
p-value [3]		0.300		0.081	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	119	4	9	
Mean (StdDev)	41.16 (11.384)	41.37 (11.535)	36.29 (8.095)	34.08 (12.905)	
Median	36.29	46.20	36.29	36.29	
Min, Max	16.5, 56.1	16.5, 56.1	26.4, 46.2	16.5, 56.1	
C3D1 CFB					
n	59	116	4	9	
LS Mean (StdErr) [2]	2.97 (1.349)	3.42 (1.008)	21.55 (4.905)	2.05 (3.736)	
95% CI [2]	0.31, 5.64	1.43, 5.41	10.46, 32.65	-6.40, 10.50	
Difference (95% CI) in CFB [2]		0.44 (-2.50, 3.38)		-19.50 (-28.79, -10.22)	
p-value [3]		0.766		0.001	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	40.53 (10.837)	42.20 (12.061)	26.37 (0.000)	32.32 (10.657)	
Median	36.29	46.20	26.37	36.29	
Min, Max	16.5, 56.1	16.5, 56.1	26.4, 26.4	16.5, 46.2	
C4D1 CFB					
n	52	115	4	10	
LS Mean (StdErr) [2]	1.77 (1.604)	4.06 (1.171)	1.65 (5.628)	-6.61 (4.309)	
95% CI [2]	-1.40, 4.94	1.75, 6.38	-10.89, 14.19	-16.21, 2.99	
Difference (95% CI) in CFB [2]		2.29 (-1.13, 5.72)		-8.26 (-18.68, 2.15)	
p-value [3]		0.188		0.108	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	115	4	10	
Mean (StdDev)	40.58 (11.740)	43.36 (11.874)	26.37 (0.000)	40.25 (12.540)	
Median	36.29	46.20	26.37	41.24	
Min, Max	16.5, 56.1	16.5, 56.1	26.4, 26.4	16.5, 56.1	
C5D1 CFB					
n	57	109	4	10	
LS Mean (StdErr) [2]	1.73 (1.617)	5.38 (1.228)	7.16 (6.764)	4.41 (5.179)	
95% CI [2]	-1.47, 4.92	2.96, 7.81	-7.91, 22.23	-7.13, 15.94	
Difference (95% CI) in CFB [2]		3.66 (0.14, 7.18)		-2.75 (-15.27, 9.76)	
p-value [3]		0.042		0.635	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	40.39 (10.834)	43.28 (11.924)	21.41 (5.724)	35.29 (10.910)	
Median	36.29	46.20	21.41	36.29	
Min, Max	16.5, 56.1	16.5, 56.1	16.5, 26.4	16.5, 46.2	
C6D1 CFB					
n	55	113	4	10	
LS Mean (StdErr) [2]	1.49 (1.641)	4.81 (1.212)	-4.96 (7.959)	-4.96 (6.094)	
95% CI [2]	-1.75, 4.73	2.42, 7.20	-22.69, 12.78	-18.53, 8.62	
Difference (95% CI) in CFB [2]		3.32 (-0.25, 6.90)		0.00 (-14.73, 14.73)	
p-value [3]		0.068		>0.999	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	41.76 (11.322)	43.49 (11.975)	23.89 (4.957)	34.30 (13.052)	
Median	36.29	46.20	26.37	36.29	
Min, Max	16.5, 56.1	16.5, 56.1	16.5, 26.4	16.5, 56.1	
C7D1 CFB					
n	55	111	4	10	
LS Mean (StdErr) [2]	1.67 (1.701)	4.72 (1.263)	4.22 (6.438)	0.18 (4.929)	
95% CI [2]	-1.69, 5.03	2.23, 7.22	-10.12, 18.57	-10.80, 11.17	
Difference (95% CI) in CFB [2]		3.05 (-0.60, 6.71)		-4.04 (-15.95, 7.87)	
Hedges'G (95% CI) in CFB		0.23 (-0.09, 0.56)		-0.25 (-1.60, 0.99)	
p-value [3]		0.100		0.467	
					0.289

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	63	125	4	10	
Mean (StdDev)	37.52 (12.214)	38.56 (11.728)	36.51 (7.125)	33.75 (12.203)	
Median	33.75	39.27	36.51	33.75	
Min, Max	11.7, 55.8	11.7, 55.8	28.2, 44.8	11.7, 55.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	40.54 (11.242)	41.73 (11.770)	33.75 (11.922)	39.88 (10.488)	
Median	39.27	44.79	36.51	39.27	
Min, Max	17.2, 55.8	11.7, 55.8	17.2, 44.8	22.7, 55.8	
C2D1 CFB					
n	61	123	4	9	
LS Mean (StdErr) [2]	3.57 (1.279)	3.68 (0.968)	1.68 (8.346)	9.24 (6.356)	
95% CI [2]	1.04, 6.09	1.77, 5.58	-17.20, 20.56	-5.14, 23.62	
Difference (95% CI) in CFB [2]		0.11 (-2.67, 2.89)		7.56 (-8.24, 23.35)	
p-value [3]		0.940		0.307	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	119	4	9	
Mean (StdDev)	41.72 (12.252)	42.01 (11.716)	30.99 (11.489)	40.50 (14.280)	
Median	44.79	44.79	30.99	44.79	
Min, Max	11.7, 55.8	11.7, 55.8	17.2, 44.8	22.7, 55.8	
C3D1 CFB					
n	59	116	4	9	
LS Mean (StdErr) [2]	4.43 (1.363)	4.27 (1.019)	-0.84 (7.455)	10.56 (5.678)	
95% CI [2]	1.74, 7.13	2.26, 6.28	-17.70, 16.02	-2.29, 23.40	
Difference (95% CI) in CFB [2]		-0.16 (-3.13, 2.81)		11.40 (-2.71, 25.51)	
p-value [3]		0.914		0.101	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	118	4	10	
Mean (StdDev)	40.26 (11.818)	43.25 (11.655)	29.61 (11.378)	35.96 (12.798)	
Median	39.27	44.79	28.23	36.51	
Min, Max	17.2, 55.8	17.2, 55.8	17.2, 44.8	11.7, 55.8	
C4D1 CFB					
n	52	114	4	10	
LS Mean (StdErr) [2]	3.92 (1.542)	5.18 (1.127)	-4.80 (7.915)	0.51 (6.060)	
95% CI [2]	0.87, 6.96	2.96, 7.41	-22.44, 12.83	-12.99, 14.01	
Difference (95% CI) in CFB [2]		1.27 (-2.03, 4.57)		5.31 (-9.33, 19.96)	
p-value [3]		0.449		0.438	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	115	4	10	
Mean (StdDev)	41.39 (12.282)	44.02 (10.387)	36.51 (9.559)	33.20 (14.590)	
Median	44.79	44.79	33.75	33.75	
Min, Max	11.7, 55.8	17.2, 55.8	28.2, 50.3	11.7, 55.8	
C5D1 CFB					
n	57	109	4	10	
LS Mean (StdErr) [2]	3.35 (1.559)	5.26 (1.184)	4.91 (8.830)	1.53 (6.761)	
95% CI [2]	0.27, 6.43	2.92, 7.59	-14.77, 24.58	-13.53, 16.60	
Difference (95% CI) in CFB [2]		1.91 (-1.48, 5.30)		-3.37 (-19.71, 12.97)	
p-value [3]		0.268		0.655	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	58	119	4	10	
Mean (StdDev)	42.32 (12.327)	43.26 (11.517)	24.09 (6.945)	33.20 (10.868)	
Median	44.79	44.79	22.71	33.75	
Min, Max	11.7, 55.8	11.7, 55.8	17.2, 33.8	17.2, 50.3	
C6D1 CFB					
n	55	113	4	10	
LS Mean (StdErr) [2]	4.33 (1.635)	4.37 (1.207)	-16.56 (9.571)	-5.52 (7.328)	
95% CI [2]	1.10, 7.55	1.99, 6.75	-37.88, 4.77	-21.85, 10.81	
Difference (95% CI) in CFB [2]		0.04 (-3.52, 3.60)		11.04 (-6.67, 28.75)	
p-value [3]		0.982		0.195	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	41.17 (12.558)	43.14 (11.418)	29.61 (11.378)	37.06 (12.798)	
Median	42.03	44.79	28.23	33.75	
Min, Max	11.7, 55.8	11.7, 55.8	17.2, 44.8	17.2, 55.8	
C7D1 CFB					
n	55	111	4	10	
LS Mean (StdErr) [2]	1.66 (1.447)	3.77 (1.075)	-4.70 (9.858)	2.56 (7.548)	
95% CI [2]	-1.20, 4.51	1.65, 5.89	-26.67, 17.26	-14.26, 19.37	
Difference (95% CI) in CFB [2]		2.11 (-0.99, 5.22)		7.26 (-10.98, 25.50)	
Hedges'G (95% CI) in CFB		0.19 (-0.13, 0.52)		0.30 (-0.94, 1.65)	
p-value [3]		0.181		0.396	
					0.208

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	63	125	4	10	
Mean (StdDev)	41.82 (9.851)	39.84 (10.173)	35.03 (3.042)	39.59 (10.730)	
Median	39.59	39.59	33.51	39.59	
Min, Max	21.3, 63.9	15.3, 63.9	33.5, 39.6	27.4, 63.9	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	42.40 (10.704)	41.78 (10.487)	39.59 (4.967)	40.95 (10.438)	
Median	39.59	39.59	39.59	39.59	
Min, Max	21.3, 63.9	15.3, 63.9	33.5, 45.7	27.4, 57.8	
C2D1 CFB					
n	61	123	4	9	
LS Mean (StdErr) [2]	0.71 (0.989)	2.37 (0.749)	13.89 (5.724)	9.46 (4.359)	
95% CI [2]	-1.24, 2.67	0.89, 3.85	0.94, 26.83	-0.41, 19.32	
Difference (95% CI) in CFB [2]		1.66 (-0.49, 3.81)		-4.43 (-15.26, 6.40)	
p-value [3]		0.129		0.379	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	119	4	9	
Mean (StdDev)	42.97 (10.580)	43.68 (10.891)	42.64 (6.083)	42.30 (13.297)	
Median	39.59	45.68	45.68	39.59	
Min, Max	15.3, 63.9	15.3, 63.9	33.5, 45.7	21.3, 63.9	
C3D1 CFB					
n	59	116	4	9	
LS Mean (StdErr) [2]	0.97 (1.150)	4.20 (0.859)	9.12 (9.542)	4.56 (7.267)	
95% CI [2]	-1.30, 3.24	2.51, 5.90	-12.46, 30.71	-11.88, 21.00	
Difference (95% CI) in CFB [2]		3.23 (0.73, 5.74)		-4.56 (-22.62, 13.50)	
p-value [3]		0.012		0.582	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	119	4	10	
Mean (StdDev)	43.18 (9.964)	44.76 (10.615)	36.55 (6.083)	38.99 (12.968)	
Median	39.59	45.68	33.51	42.64	
Min, Max	21.3, 63.9	21.3, 63.9	33.5, 45.7	15.3, 57.8	
C4D1 CFB					
n	52	115	4	10	
LS Mean (StdErr) [2]	2.28 (1.259)	5.63 (0.919)	5.29 (9.797)	2.48 (7.501)	
95% CI [2]	-0.21, 4.76	3.81, 7.45	-16.53, 27.12	-14.23, 19.19	
Difference (95% CI) in CFB [2]		3.35 (0.66, 6.04)		-2.82 (-20.94, 15.31)	
p-value [3]		0.015		0.736	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	115	4	10	
Mean (StdDev)	43.24 (11.211)	44.14 (10.187)	39.59 (4.967)	40.81 (12.434)	
Median	39.59	45.68	39.59	39.59	
Min, Max	21.3, 63.9	15.3, 63.9	33.5, 45.7	21.3, 63.9	
C5D1 CFB					
n	57	109	4	10	
LS Mean (StdErr) [2]	1.06 (1.294)	4.18 (0.982)	11.15 (7.975)	7.10 (6.106)	
95% CI [2]	-1.49, 3.62	2.24, 6.12	-6.62, 28.92	-6.51, 20.70	
Difference (95% CI) in CFB [2]		3.12 (0.30, 5.94)		-4.06 (-18.81, 10.70)	
p-value [3]		0.030		0.554	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	57	119	4	10	
Mean (StdDev)	43.76 (9.966)	43.84 (10.700)	33.51 (0.000)	40.20 (10.901)	
Median	45.68	45.68	33.51	39.59	
Min, Max	27.4, 63.9	15.3, 63.9	33.5, 33.5	27.4, 63.9	
C6D1 CFB					
n	54	113	4	10	
LS Mean (StdErr) [2]	1.55 (1.310)	4.49 (0.963)	-4.62 (6.175)	-1.13 (4.728)	
95% CI [2]	-1.04, 4.13	2.59, 6.40	-18.38, 9.14	-11.66, 9.41	
Difference (95% CI) in CFB [2]		2.95 (0.09, 5.80)		3.49 (-7.93, 14.92)	
p-value [3]		0.043		0.511	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	43.37 (11.037)	44.53 (11.462)	38.07 (9.125)	37.77 (13.157)	
Median	45.68	45.68	39.59	39.59	
Min, Max	15.3, 63.9	15.3, 63.9	27.4, 45.7	15.3, 63.9	
C7D1 CFB					
n	55	111	4	10	
LS Mean (StdErr) [2]	1.03 (1.481)	4.67 (1.100)	4.73 (9.733)	0.34 (7.452)	
95% CI [2]	-1.90, 3.95	2.49, 6.84	-16.95, 26.42	-16.27, 16.94	
Difference (95% CI) in CFB [2]		3.64 (0.46, 6.82)		-4.39 (-22.40, 13.62)	
Hedges'G (95% CI) in CFB		0.32 (-0.01, 0.65)		-0.18 (-1.51, 1.07)	
p-value [3]		0.025		0.599	
					0.153

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	63	124	4	10	
Mean (StdDev)	34.95 (10.294)	34.54 (10.828)	20.22 (7.592)	25.07 (4.969)	
Median	33.69	34.58	18.98	25.14	
Min, Max	15.6, 60.4	10.5, 61.8	13.8, 29.1	15.1, 31.3	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	37.33 (10.809)	38.42 (11.973)	24.34 (2.854)	27.80 (9.312)	
Median	36.83	39.95	24.53	26.28	
Min, Max	16.5, 61.2	13.0, 58.5	20.9, 27.4	16.6, 47.3	
C2D1 CFB					
n	61	122	4	9	
LS Mean (StdErr) [2]	0.85 (0.958)	2.41 (0.731)	10.78 (3.619)	7.47 (2.756)	
95% CI [2]	-1.04, 2.74	0.96, 3.85	2.59, 18.97	1.24, 13.71	
Difference (95% CI) in CFB [2]		1.55 (-0.53, 3.63)		-3.31 (-10.16, 3.54)	
p-value [3]		0.143		0.303	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	119	4	9	
Mean (StdDev)	37.00 (9.865)	39.65 (12.038)	23.09 (6.109)	27.10 (6.174)	
Median	36.41	40.14	22.80	26.29	
Min, Max	15.1, 62.6	13.3, 61.4	17.7, 29.1	19.4, 40.1	
C3D1 CFB					
n	59	115	4	9	
LS Mean (StdErr) [2]	1.43 (1.004)	4.52 (0.757)	5.78 (1.834)	3.78 (1.397)	
95% CI [2]	-0.55, 3.41	3.03, 6.02	1.63, 9.93	0.62, 6.94	
Difference (95% CI) in CFB [2]		3.09 (0.90, 5.28)		-2.00 (-5.47, 1.47)	
p-value [3]		0.006		0.224	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	116	4	10	
Mean (StdDev)	37.39 (10.516)	39.87 (11.462)	26.11 (4.935)	28.94 (8.754)	
Median	36.80	41.13	25.83	25.19	
Min, Max	10.8, 61.5	12.8, 59.8	21.0, 31.8	18.0, 42.1	
C4D1 CFB					
n	52	111	4	10	
LS Mean (StdErr) [2]	1.63 (1.157)	4.18 (0.874)	9.14 (4.059)	5.88 (3.108)	
95% CI [2]	-0.66, 3.91	2.46, 5.91	0.09, 18.18	-1.05, 12.80	
Difference (95% CI) in CFB [2]		2.56 (0.09, 5.03)		-3.26 (-10.77, 4.25)	
p-value [3]		0.043		0.356	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	115	4	10	
Mean (StdDev)	37.61 (10.743)	39.73 (12.135)	22.04 (7.077)	29.28 (6.781)	
Median	39.45	39.67	22.95	27.86	
Min, Max	15.9, 60.1	13.0, 64.3	13.5, 28.8	21.3, 38.8	
C5D1 CFB					
n	57	108	4	10	
LS Mean (StdErr) [2]	1.75 (1.130)	4.57 (0.866)	3.72 (2.482)	5.80 (1.901)	
95% CI [2]	-0.48, 3.99	2.86, 6.28	-1.81, 9.25	1.57, 10.04	
Difference (95% CI) in CFB [2]		2.81 (0.35, 5.28)		2.08 (-2.51, 6.67)	
p-value [3]		0.025		0.337	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	57	119	4	10	
Mean (StdDev)	36.59 (10.870)	41.48 (11.582)	22.93 (4.857)	28.17 (8.201)	
Median	36.34	43.29	22.18	27.02	
Min, Max	16.4, 58.8	17.3, 61.0	18.3, 29.0	18.0, 41.9	
C6D1 CFB					
n	54	112	4	10	
LS Mean (StdErr) [2]	0.48 (1.151)	5.72 (0.854)	4.77 (4.098)	5.27 (3.137)	
95% CI [2]	-1.80, 2.75	4.03, 7.40	-4.36, 13.90	-1.72, 12.26	
Difference (95% CI) in CFB [2]		5.24 (2.73, 7.75)		0.50 (-7.08, 8.08)	
p-value [3]		<0.0001		0.886	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	38.60 (10.391)	40.79 (12.122)	21.68 (5.596)	29.18 (8.272)	
Median	38.15	40.29	22.33	26.19	
Min, Max	19.0, 63.2	12.5, 63.1	14.5, 27.6	18.0, 44.7	
C7D1 CFB					
n	55	110	4	10	
LS Mean (StdErr) [2]	1.55 (1.203)	4.19 (0.902)	6.62 (4.556)	8.21 (3.488)	
95% CI [2]	-0.83, 3.93	2.41, 5.98	-3.54, 16.77	0.44, 15.99	
Difference (95% CI) in CFB [2]		2.64 (0.06, 5.23)		1.60 (-6.83, 10.03)	
Hedges'G (95% CI) in CFB		0.28 (-0.04, 0.61)		0.14 (-1.12, 1.46)	
p-value [3]		0.045		0.682	
					0.980

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
Baseline					
n	63	124	4	10	
Mean (StdDev)	41.27 (10.890)	40.64 (10.621)	36.66 (4.963)	40.06 (9.524)	
Median	39.58	40.91	36.21	40.25	
Min, Max	19.2, 63.9	13.2, 64.0	32.3, 41.9	27.3, 59.9	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C2D1					
n	65	128	4	9	
Mean (StdDev)	42.71 (11.110)	42.48 (10.535)	40.36 (7.729)	43.43 (8.531)	
Median	42.49	42.49	42.21	44.44	
Min, Max	19.9, 64.4	19.0, 64.8	29.4, 47.6	28.5, 57.4	
C2D1 CFB					
n	61	122	4	9	
LS Mean (StdErr) [2]	1.90 (1.094)	2.74 (0.835)	6.15 (6.861)	5.19 (5.225)	
95% CI [2]	-0.26, 4.06	1.09, 4.39	-9.37, 21.67	-6.63, 17.01	
Difference (95% CI) in CFB [2]		0.85 (-1.53, 3.23)		-0.96 (-13.95, 12.02)	
p-value [3]		0.483		0.871	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C3D1					
n	63	119	4	9	
Mean (StdDev)	43.86 (11.129)	43.33 (10.534)	42.81 (4.251)	43.59 (11.649)	
Median	44.46	45.31	41.97	44.64	
Min, Max	11.2, 63.3	13.8, 66.0	38.9, 48.4	22.7, 56.7	
C3D1 CFB					
n	59	115	4	9	
LS Mean (StdErr) [2]	2.72 (1.141)	3.42 (0.861)	9.17 (6.871)	5.98 (5.233)	
95% CI [2]	0.46, 4.97	1.72, 5.12	-6.38, 24.71	-5.86, 17.81	
Difference (95% CI) in CFB [2]		0.70 (-1.79, 3.19)		-3.19 (-16.20, 9.81)	
p-value [3]		0.578		0.592	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C4D1					
n	56	116	4	10	
Mean (StdDev)	42.79 (10.187)	44.69 (10.668)	36.03 (5.838)	39.77 (11.471)	
Median	41.22	45.75	33.48	41.03	
Min, Max	22.0, 59.7	13.7, 63.9	32.4, 44.7	16.0, 58.4	
C4D1 CFB					
n	52	111	4	10	
LS Mean (StdErr) [2]	2.40 (1.344)	4.63 (1.016)	0.32 (8.811)	-0.65 (6.746)	
95% CI [2]	-0.26, 5.05	2.63, 6.64	-19.32, 19.95	-15.68, 14.38	
Difference (95% CI) in CFB [2]		2.24 (-0.63, 5.11)		-0.96 (-17.27, 15.34)	
p-value [3]		0.126		0.898	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C5D1					
n	60	115	4	10	
Mean (StdDev)	43.37 (11.893)	44.88 (10.389)	39.72 (6.690)	41.74 (11.961)	
Median	44.80	46.62	37.59	41.81	
Min, Max	14.1, 61.6	19.5, 64.4	34.4, 49.3	21.3, 57.8	
C5D1 CFB					
n	57	108	4	10	
LS Mean (StdErr) [2]	1.94 (1.412)	4.39 (1.081)	7.90 (7.606)	4.52 (5.824)	
95% CI [2]	-0.85, 4.72	2.26, 6.53	-9.05, 24.85	-8.46, 17.50	
Difference (95% CI) in CFB [2]		2.46 (-0.62, 5.53)		-3.38 (-17.45, 10.69)	
p-value [3]		0.116		0.604	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C6D1					
n	57	119	4	10	
Mean (StdDev)	44.27 (10.264)	44.14 (10.960)	30.39 (4.363)	40.52 (9.546)	
Median	43.94	46.04	30.75	43.76	
Min, Max	24.1, 61.4	12.1, 61.5	24.8, 35.2	26.2, 52.8	
C6D1 CFB					
n	54	112	4	10	
LS Mean (StdErr) [2]	2.76 (1.407)	3.79 (1.044)	-10.70 (5.976)	-3.62 (4.576)	
95% CI [2]	-0.02, 5.54	1.73, 5.85	-24.02, 2.61	-13.81, 6.58	
Difference (95% CI) in CFB [2]		1.03 (-2.04, 4.10)		7.09 (-3.97, 18.14)	
p-value [3]		0.507		0.184	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.7a
Change from Baseline of SF-12 by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	ECOG Status = 0 or 1		ECOG Status = 2+		
	Placebo (N=67)	Avapritinib 25 mg (N=131)	Placebo (N=4)	Avapritinib 25 mg (N=10)	Test of Interaction p-value [1]
C7D1					
n	58	117	4	10	
Mean (StdDev)	43.61 (11.412)	44.52 (11.146)	36.25 (11.732)	41.13 (13.665)	
Median	43.46	45.10	37.21	44.38	
Min, Max	12.1, 64.9	12.0, 63.3	21.4, 49.2	14.2, 60.7	
C7D1 CFB					
n	55	110	4	10	
LS Mean (StdErr) [2]	1.66 (1.380)	4.09 (1.035)	-0.41 (9.474)	0.26 (7.254)	
95% CI [2]	-1.07, 4.38	2.05, 6.14	-21.52, 20.70	-15.90, 16.42	
Difference (95% CI) in CFB [2]		2.44 (-0.53, 5.40)		0.68 (-16.86, 18.21)	
Hedges'G (95% CI) in CFB		0.23 (-0.10, 0.56)		0.03 (-1.25, 1.32)	
p-value [3]		0.106		0.933	
					0.832

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-ecog-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	63	125	
Mean (StdDev)	43.89 (10.862)	36.32 (13.854)	37.68 (12.157)	37.53 (11.354)	
Median	43.89	35.48	39.69	39.69	
Min, Max	31.3, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	46.00 (8.056)	38.84 (14.547)	39.94 (11.227)	40.81 (11.822)	
Median	43.89	35.48	39.69	39.69	
Min, Max	39.7, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C2D1 CFB					
n	4	10	61	122	
LS Mean (StdErr) [2]	3.33 (2.855)	5.08 (2.855)	1.38 (1.068)	2.32 (0.806)	
95% CI [2]	-3.03, 9.69	-1.28, 11.44	-0.73, 3.49	0.73, 3.91	
Difference (95% CI) in CFB [2]		1.75 (-6.34, 9.84)		0.94 (-1.36, 3.24)	
p-value [3]		0.641		0.420	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	118	
Mean (StdDev)	48.10 (6.870)	40.53 (15.078)	39.15 (10.456)	41.11 (11.864)	
Median	48.10	39.69	39.69	39.69	
Min, Max	39.7, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C3D1 CFB					
n	4	10	59	115	
LS Mean (StdErr) [2]	4.89 (4.257)	6.32 (4.257)	1.41 (1.124)	3.45 (0.837)	
95% CI [2]	-4.59, 14.38	-3.16, 15.81	-0.81, 3.63	1.80, 5.10	
Difference (95% CI) in CFB [2]		1.43 (-10.64, 13.49)		2.04 (-0.39, 4.47)	
p-value [3]		0.797		0.100	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	45.29 (9.716)	41.56 (13.811)	39.54 (10.958)	41.44 (11.539)	
Median	39.69	39.69	39.69	39.69	
Min, Max	39.7, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C4D1 CFB					
n	3	9	53	116	
LS Mean (StdErr) [2]	8.41 (5.153)	7.36 (3.864)	2.62 (1.278)	4.32 (0.941)	
95% CI [2]	-3.47, 20.30	-1.55, 16.27	0.09, 5.14	2.47, 6.18	
Difference (95% CI) in CFB [2]		-1.05 (-14.66, 12.56)		1.71 (-1.01, 4.43)	
p-value [3]		0.863		0.217	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	117	
Mean (StdDev)	46.00 (4.207)	39.69 (14.917)	39.97 (12.390)	41.84 (11.596)	
Median	48.10	35.48	39.69	39.69	
Min, Max	39.7, 48.1	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C5D1 CFB					
n	4	8	57	111	
LS Mean (StdErr) [2]	3.24 (5.485)	5.18 (5.485)	1.82 (1.254)	4.42 (0.945)	
95% CI [2]	-9.41, 15.88	-7.47, 17.83	-0.65, 4.30	2.55, 6.28	
Difference (95% CI) in CFB [2]		1.94 (-14.24, 18.12)		2.59 (-0.10, 5.29)	
p-value [3]		0.789		0.059	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	46.00 (8.056)	42.49 (14.574)	38.81 (11.440)	42.56 (12.073)	
Median	43.89	39.69	39.69	39.69	
Min, Max	39.7, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C6D1 CFB					
n	4	9	55	114	
LS Mean (StdErr) [2]	2.74 (3.871)	5.67 (3.871)	0.70 (1.267)	4.70 (0.930)	
95% CI [2]	-6.01, 11.50	-3.09, 14.43	-1.81, 3.20	2.87, 6.54	
Difference (95% CI) in CFB [2]		2.93 (-8.24, 14.09)		4.01 (1.28, 6.73)	
p-value [3]		0.568		0.004	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Functioning T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	43.89 (8.414)	42.84 (15.539)	39.69 (11.474)	42.09 (12.156)	
Median	39.69	48.10	39.69	39.69	
Min, Max	39.7, 56.5	22.9, 56.5	22.9, 56.5	22.9, 56.5	
C7D1 CFB					
n	4	8	55	113	
LS Mean (StdErr) [2]	-0.11 (4.411)	5.72 (4.411)	0.75 (1.436)	3.79 (1.060)	
95% CI [2]	-10.28, 10.06	-4.45, 15.89	-2.08, 3.59	1.69, 5.88	
Difference (95% CI) in CFB [2]		5.83 (-7.19, 18.84)		3.04 (-0.00, 6.07)	
Hedges'G (95% CI) in CFB		0.47 (-0.80, 1.97)		0.27 (-0.05, 0.60)	
p-value [3]		0.332		0.050	
					0.857

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	63	125	
Mean (StdDev)	37.88 (11.807)	30.92 (10.105)	34.37 (7.519)	35.09 (8.514)	
Median	39.00	30.03	34.51	34.51	
Min, Max	25.5, 48.0	21.0, 48.0	21.0, 52.5	21.0, 57.0	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	39.00 (13.216)	35.41 (11.357)	36.24 (9.176)	37.80 (10.030)	
Median	41.25	34.51	34.51	39.00	
Min, Max	21.0, 52.5	21.0, 52.5	21.0, 57.0	21.0, 57.0	
C2D1 CFB					
n	4	10	61	122	
LS Mean (StdErr) [2]	-1.20 (5.442)	2.70 (5.442)	1.05 (0.975)	1.86 (0.736)	
95% CI [2]	-13.33, 10.93	-9.43, 14.82	-0.87, 2.98	0.41, 3.31	
Difference (95% CI) in CFB [2]		3.90 (-11.53, 19.32)		0.81 (-1.29, 2.91)	
p-value [3]		0.586		0.449	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	118	
Mean (StdDev)	39.00 (9.698)	37.66 (10.379)	36.65 (9.738)	39.35 (10.270)	
Median	36.76	36.76	34.51	39.00	
Min, Max	30.0, 52.5	21.0, 48.0	21.0, 57.0	21.0, 57.0	
C3D1 CFB					
n	4	10	59	115	
LS Mean (StdErr) [2]	-1.30 (3.932)	4.29 (3.932)	1.88 (1.109)	4.11 (0.826)	
95% CI [2]	-10.06, 7.46	-4.47, 13.05	-0.31, 4.07	2.48, 5.74	
Difference (95% CI) in CFB [2]		5.59 (-5.55, 16.73)		2.23 (-0.17, 4.63)	
p-value [3]		0.290		0.069	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	118	
Mean (StdDev)	43.49 (7.776)	40.00 (11.830)	36.56 (10.077)	39.92 (10.193)	
Median	47.98	43.49	39.00	39.00	
Min, Max	34.5, 48.0	21.0, 52.5	21.0, 57.0	21.0, 57.0	
C4D1 CFB					
n	3	9	53	114	
LS Mean (StdErr) [2]	11.22 (5.939)	8.42 (4.454)	1.87 (1.183)	4.40 (0.880)	
95% CI [2]	-2.47, 24.92	-1.85, 18.69	-0.46, 4.21	2.66, 6.14	
Difference (95% CI) in CFB [2]		-2.81 (-18.50, 12.88)		2.53 (0.01, 5.05)	
p-value [3]		0.691		0.049	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	117	
Mean (StdDev)	43.49 (6.349)	37.32 (11.239)	36.76 (9.442)	39.77 (9.974)	
Median	45.74	34.51	39.00	39.00	
Min, Max	34.5, 48.0	25.5, 52.5	21.0, 57.0	21.0, 57.0	
C5D1 CFB					
n	4	8	57	111	
LS Mean (StdErr) [2]	5.30 (4.753)	6.68 (4.753)	1.98 (1.146)	4.62 (0.864)	
95% CI [2]	-5.67, 16.26	-4.28, 17.64	-0.28, 4.24	2.92, 6.33	
Difference (95% CI) in CFB [2]		1.38 (-12.64, 15.40)		2.64 (0.18, 5.10)	
p-value [3]		0.826		0.036	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	40.13 (9.255)	39.50 (11.759)	35.83 (9.950)	40.91 (10.159)	
Median	41.25	39.00	34.51	39.00	
Min, Max	30.0, 48.0	21.0, 52.5	21.0, 57.0	21.0, 57.0	
C6D1 CFB					
n	4	9	55	114	
LS Mean (StdErr) [2]	0.41 (6.174)	5.58 (6.174)	1.10 (1.221)	5.33 (0.896)	
95% CI [2]	-13.56, 14.37	-8.39, 19.55	-1.31, 3.52	3.56, 7.10	
Difference (95% CI) in CFB [2]		5.17 (-12.64, 22.98)		4.22 (1.59, 6.85)	
p-value [3]		0.528		0.002	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Physical T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	42.37 (6.734)	42.37 (11.191)	37.69 (10.604)	40.40 (10.725)	
Median	43.49	45.74	39.00	39.00	
Min, Max	34.5, 48.0	25.5, 57.0	21.0, 57.0	21.0, 57.0	
C7D1 CFB					
n	4	8	55	113	
LS Mean (StdErr) [2]	4.14 (5.672)	9.32 (5.672)	2.32 (1.323)	4.47 (0.977)	
95% CI [2]	-8.94, 17.22	-3.76, 22.40	-0.29, 4.93	2.55, 6.40	
Difference (95% CI) in CFB [2]		5.18 (-11.55, 21.91)		2.16 (-0.64, 4.95)	
Hedges'G (95% CI) in CFB		0.32 (-0.97, 1.78)		0.21 (-0.11, 0.54)	
p-value [3]		0.496		0.130	
					0.704

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	63	124	
Mean (StdDev)	36.27 (11.859)	27.03 (11.303)	32.19 (10.841)	32.62 (11.581)	
Median	36.27	26.00	26.00	31.13	
Min, Max	26.0, 46.5	15.7, 46.5	15.7, 56.8	15.7, 56.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	43.97 (15.406)	32.16 (13.864)	35.32 (11.002)	39.02 (12.374)	
Median	46.54	31.13	36.27	36.27	
Min, Max	26.0, 56.8	15.7, 46.5	15.7, 56.8	15.7, 56.8	
C2D1 CFB					
n	4	10	61	121	
LS Mean (StdErr) [2]	7.56 (5.073)	2.71 (5.073)	1.27 (1.427)	4.92 (1.086)	
95% CI [2]	-3.75, 18.86	-8.59, 14.02	-1.54, 4.09	2.78, 7.07	
Difference (95% CI) in CFB [2]		-4.84 (-19.22, 9.53)		3.65 (0.58, 6.72)	
p-value [3]		0.470		0.020	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	118	
Mean (StdDev)	46.54 (14.525)	34.21 (13.522)	36.11 (10.833)	40.10 (11.844)	
Median	51.67	36.27	36.27	46.54	
Min, Max	26.0, 56.8	15.7, 46.5	15.7, 56.8	15.7, 56.8	
C3D1 CFB					
n	4	10	59	114	
LS Mean (StdErr) [2]	11.14 (5.382)	9.40 (5.382)	3.46 (1.348)	7.63 (1.014)	
95% CI [2]	-0.85, 23.13	-2.59, 21.39	0.80, 6.12	5.63, 9.63	
Difference (95% CI) in CFB [2]		-1.74 (-17.00, 13.51)		4.17 (1.25, 7.09)	
p-value [3]		0.804		0.005	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	119	
Mean (StdDev)	39.69 (5.930)	37.41 (11.982)	36.09 (10.892)	39.29 (12.780)	
Median	36.27	46.54	36.27	36.27	
Min, Max	36.3, 46.5	15.7, 46.5	15.7, 56.8	15.7, 56.8	
C4D1 CFB					
n	3	9	53	114	
LS Mean (StdErr) [2]	14.76 (5.034)	10.59 (3.775)	2.36 (1.567)	5.66 (1.181)	
95% CI [2]	3.16, 26.37	1.89, 19.30	-0.74, 5.45	3.33, 7.99	
Difference (95% CI) in CFB [2]		-4.17 (-17.47, 9.13)		3.30 (-0.03, 6.63)	
p-value [3]		0.490		0.052	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	117	
Mean (StdDev)	46.54 (8.386)	34.98 (13.929)	35.41 (12.003)	39.52 (12.981)	
Median	46.54	41.40	36.27	36.27	
Min, Max	36.3, 56.8	15.7, 46.5	15.7, 56.8	15.7, 56.8	
C5D1 CFB					
n	4	8	57	110	
LS Mean (StdErr) [2]	13.04 (6.161)	7.51 (6.161)	1.47 (1.519)	6.06 (1.156)	
95% CI [2]	-1.17, 27.24	-6.70, 21.71	-1.53, 4.47	3.78, 8.34	
Difference (95% CI) in CFB [2]		-5.53 (-23.70, 12.64)		4.59 (1.33, 7.85)	
p-value [3]		0.503		0.006	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	57	120	
Mean (StdDev)	46.54 (11.859)	38.55 (16.058)	34.65 (12.547)	40.46 (12.666)	
Median	46.54	46.54	36.27	46.54	
Min, Max	36.3, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C6D1 CFB					
n	4	9	54	113	
LS Mean (StdErr) [2]	11.05 (7.542)	9.49 (7.542)	1.00 (1.509)	6.93 (1.113)	
95% CI [2]	-6.01, 28.11	-7.57, 26.55	-1.98, 3.98	4.73, 9.13	
Difference (95% CI) in CFB [2]		-1.56 (-23.32, 20.19)		5.93 (2.68, 9.18)	
p-value [3]		0.874		<0.001	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Bodily Pain T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	46.54 (8.386)	42.69 (14.460)	37.15 (11.428)	39.46 (13.421)	
Median	46.54	46.54	36.27	36.27	
Min, Max	36.3, 56.8	15.7, 56.8	15.7, 56.8	15.7, 56.8	
C7D1 CFB					
n	4	8	55	112	
LS Mean (StdErr) [2]	11.72 (7.001)	15.67 (7.001)	1.68 (1.517)	4.09 (1.132)	
95% CI [2]	-4.43, 27.86	-0.48, 31.81	-1.32, 4.67	1.86, 6.33	
Difference (95% CI) in CFB [2]		3.95 (-16.70, 24.60)		2.41 (-0.80, 5.62)	
Hedges'G (95% CI) in CFB		0.20 (-1.12, 1.62)		0.20 (-0.12, 0.53)	
p-value [3]		0.671		0.139	
					>0.999

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	63	125	
Mean (StdDev)	37.48 (8.586)	29.41 (7.014)	33.59 (10.520)	34.18 (9.745)	
Median	37.48	30.05	30.05	30.05	
Min, Max	30.0, 44.9	19.4, 44.9	19.4, 61.9	19.4, 55.5	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	37.48 (8.586)	30.90 (8.569)	36.12 (11.045)	36.18 (10.788)	
Median	37.48	30.05	30.05	30.05	
Min, Max	30.0, 44.9	19.4, 44.9	19.4, 55.5	19.4, 55.5	
C2D1 CFB					
n	4	10	61	122	
LS Mean (StdErr) [2]	0.23 (3.033)	4.72 (3.033)	1.86 (1.211)	1.90 (0.914)	
95% CI [2]	-6.52, 6.99	-2.03, 11.48	-0.53, 4.25	0.09, 3.70	
Difference (95% CI) in CFB [2]		4.49 (-4.11, 13.09)		0.03 (-2.58, 2.64)	
p-value [3]		0.272		0.980	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	118	
Mean (StdDev)	41.20 (7.436)	36.42 (9.501)	34.80 (10.065)	37.50 (11.190)	
Median	44.92	37.48	30.05	30.05	
Min, Max	30.0, 44.9	19.4, 44.9	19.4, 55.5	19.4, 61.9	
C3D1 CFB					
n	4	10	59	115	
LS Mean (StdErr) [2]	2.27 (3.660)	7.64 (3.660)	0.26 (1.313)	3.27 (0.979)	
95% CI [2]	-5.88, 10.43	-0.51, 15.80	-2.33, 2.86	1.33, 5.20	
Difference (95% CI) in CFB [2]		5.37 (-5.00, 15.75)		3.00 (0.16, 5.84)	
p-value [3]		0.275		0.038	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	35.00 (8.586)	39.96 (11.091)	36.05 (10.819)	37.34 (11.034)	
Median	30.05	44.92	30.05	44.92	
Min, Max	30.0, 44.9	19.4, 55.5	19.4, 61.9	19.4, 55.5	
C4D1 CFB					
n	3	9	53	116	
LS Mean (StdErr) [2]	-2.26 (7.028)	13.08 (5.271)	1.17 (1.398)	2.36 (1.029)	
95% CI [2]	-18.46, 13.95	0.92, 25.23	-1.59, 3.93	0.33, 4.40	
Difference (95% CI) in CFB [2]		15.34 (-3.23, 33.90)		1.20 (-1.78, 4.18)	
p-value [3]		0.093		0.428	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	117	
Mean (StdDev)	41.20 (7.436)	39.34 (11.689)	35.99 (10.221)	37.93 (10.783)	
Median	44.92	44.92	30.05	44.92	
Min, Max	30.0, 44.9	19.4, 55.5	19.4, 61.9	19.4, 55.5	
C5D1 CFB					
n	4	8	57	111	
LS Mean (StdErr) [2]	4.14 (5.222)	14.27 (5.222)	1.82 (1.387)	3.47 (1.045)	
95% CI [2]	-7.90, 16.18	2.23, 26.32	-0.92, 4.56	1.40, 5.53	
Difference (95% CI) in CFB [2]		10.13 (-5.27, 25.54)		1.64 (-1.33, 4.62)	
p-value [3]		0.168		0.277	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	41.20 (7.436)	38.78 (12.723)	35.91 (11.391)	38.74 (10.962)	
Median	44.92	44.92	30.05	44.92	
Min, Max	30.0, 44.9	19.4, 55.5	19.4, 61.9	19.4, 55.5	
C6D1 CFB					
n	4	9	55	114	
LS Mean (StdErr) [2]	4.22 (5.206)	14.19 (5.206)	1.37 (1.371)	4.23 (1.006)	
95% CI [2]	-7.56, 16.00	2.42, 25.97	-1.34, 4.08	2.25, 6.22	
Difference (95% CI) in CFB [2]		9.98 (-5.04, 24.99)		2.86 (-0.09, 5.81)	
p-value [3]		0.167		0.057	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

General Health T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	41.20 (7.436)	42.53 (8.531)	36.35 (11.021)	38.78 (11.087)	
Median	44.92	44.92	30.05	44.92	
Min, Max	30.0, 44.9	30.0, 55.5	19.4, 55.5	19.4, 55.5	
C7D1 CFB					
n	4	8	55	113	
LS Mean (StdErr) [2]	3.16 (3.877)	15.25 (3.877)	0.79 (1.449)	3.64 (1.070)	
95% CI [2]	-5.78, 12.10	6.31, 24.19	-2.07, 3.66	1.53, 5.75	
Difference (95% CI) in CFB [2]		12.09 (0.66, 23.53)		2.84 (-0.22, 5.91)	
Hedges'G (95% CI) in CFB		1.10 (-0.10, 2.86)		0.25 (-0.07, 0.58)	
p-value [3]		0.041		0.069	
					0.394

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	63	125	
Mean (StdDev)	43.13 (9.754)	34.35 (6.820)	39.18 (8.883)	37.86 (8.438)	
Median	38.25	33.37	38.25	38.25	
Min, Max	38.2, 57.8	28.5, 48.0	28.5, 57.8	28.5, 57.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	45.56 (4.877)	40.20 (11.990)	40.50 (9.086)	39.94 (9.366)	
Median	48.00	38.25	38.25	38.25	
Min, Max	38.2, 48.0	28.5, 57.8	28.5, 67.5	28.5, 57.8	
C2D1 CFB					
n	4	10	61	122	
LS Mean (StdErr) [2]	2.30 (5.342)	7.45 (5.342)	1.18 (1.111)	2.35 (0.838)	
95% CI [2]	-9.60, 14.20	-4.45, 19.36	-1.01, 3.38	0.70, 4.00	
Difference (95% CI) in CFB [2]		5.15 (-9.99, 20.29)		1.17 (-1.23, 3.56)	
p-value [3]		0.466		0.337	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	118	
Mean (StdDev)	40.69 (9.339)	42.15 (11.449)	41.66 (9.621)	40.73 (9.728)	
Median	43.13	43.13	38.25	38.25	
Min, Max	28.5, 48.0	28.5, 57.8	28.5, 67.5	28.5, 57.8	
C3D1 CFB					
n	4	10	59	115	
LS Mean (StdErr) [2]	-2.85 (5.758)	12.61 (5.758)	2.73 (1.104)	3.02 (0.823)	
95% CI [2]	-15.68, 9.98	-0.22, 25.44	0.55, 4.91	1.39, 4.64	
Difference (95% CI) in CFB [2]		15.46 (-0.86, 31.78)		0.29 (-2.10, 2.68)	
p-value [3]		0.061		0.812	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	48.00 (0.000)	42.58 (12.056)	39.79 (8.604)	41.01 (10.130)	
Median	48.00	48.00	38.25	38.25	
Min, Max	48.0, 48.0	28.5, 57.8	28.5, 57.8	28.5, 57.8	
C4D1 CFB					
n	3	9	53	116	
LS Mean (StdErr) [2]	17.68 (4.623)	10.67 (3.467)	0.35 (1.384)	2.27 (1.018)	
95% CI [2]	7.02, 28.34	2.67, 18.66	-2.38, 3.08	0.26, 4.28	
Difference (95% CI) in CFB [2]		-7.01 (-19.22, 5.20)		1.92 (-1.03, 4.87)	
p-value [3]		0.222		0.200	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	117	
Mean (StdDev)	48.00 (7.964)	41.91 (11.585)	40.20 (9.297)	41.50 (9.921)	
Median	48.00	48.00	38.25	38.25	
Min, Max	38.2, 57.8	28.5, 57.8	28.5, 57.8	28.5, 67.5	
C5D1 CFB					
n	4	8	57	111	
LS Mean (StdErr) [2]	5.50 (5.028)	10.75 (5.028)	1.31 (1.382)	3.57 (1.041)	
95% CI [2]	-6.09, 17.10	-0.84, 22.35	-1.42, 4.04	1.52, 5.63	
Difference (95% CI) in CFB [2]		5.25 (-9.58, 20.09)		2.26 (-0.71, 5.23)	
p-value [3]		0.438		0.134	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	43.13 (5.631)	43.67 (12.056)	39.09 (9.187)	42.56 (9.860)	
Median	43.13	38.25	38.25	43.13	
Min, Max	38.2, 48.0	28.5, 57.8	28.5, 57.8	28.5, 67.5	
C6D1 CFB					
n	4	9	55	114	
LS Mean (StdErr) [2]	0.32 (4.508)	9.44 (4.508)	0.34 (1.312)	4.35 (0.963)	
95% CI [2]	-9.88, 10.52	-0.76, 19.63	-2.25, 2.93	2.44, 6.25	
Difference (95% CI) in CFB [2]		9.12 (-3.89, 22.12)		4.00 (1.18, 6.83)	
p-value [3]		0.147		0.006	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Vitality T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	48.00 (7.964)	45.56 (12.502)	41.11 (10.497)	41.86 (10.227)	
Median	48.00	48.00	38.25	38.25	
Min, Max	38.2, 57.8	28.5, 57.8	28.5, 67.5	28.5, 67.5	
C7D1 CFB					
n	4	8	55	113	
LS Mean (StdErr) [2]	6.00 (5.806)	13.51 (5.806)	2.23 (1.335)	3.60 (0.986)	
95% CI [2]	-7.39, 19.39	0.12, 26.89	-0.41, 4.86	1.65, 5.54	
Difference (95% CI) in CFB [2]		7.50 (-9.63, 24.63)		1.37 (-1.46, 4.19)	
Hedges'G (95% CI) in CFB		0.46 (-0.81, 1.96)		0.13 (-0.19, 0.46)	
p-value [3]		0.342		0.340	
					0.522

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	63	125	
Mean (StdDev)	38.76 (4.957)	34.30 (12.187)	36.92 (12.060)	37.95 (11.101)	
Median	36.29	36.29	36.29	36.29	
Min, Max	36.3, 46.2	16.5, 56.1	16.5, 56.1	16.5, 56.1	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	38.76 (4.957)	35.29 (11.869)	39.95 (11.163)	41.36 (11.232)	
Median	36.29	36.29	36.29	46.20	
Min, Max	36.3, 46.2	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C2D1 CFB					
n	4	10	61	122	
LS Mean (StdErr) [2]	-0.59 (3.664)	3.90 (3.664)	2.09 (1.456)	3.00 (1.098)	
95% CI [2]	-8.76, 7.57	-4.27, 12.06	-0.78, 4.97	0.83, 5.17	
Difference (95% CI) in CFB [2]		4.49 (-5.90, 14.87)		0.91 (-2.22, 4.05)	
p-value [3]		0.358		0.567	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	118	
Mean (StdDev)	41.24 (5.724)	38.27 (14.630)	40.85 (11.516)	41.07 (11.501)	
Median	41.24	41.24	36.29	41.24	
Min, Max	36.3, 46.2	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C3D1 CFB					
n	4	10	59	115	
LS Mean (StdErr) [2]	2.90 (4.822)	7.01 (4.822)	3.91 (1.390)	3.14 (1.035)	
95% CI [2]	-7.84, 13.64	-3.73, 17.76	1.16, 6.65	1.10, 5.19	
Difference (95% CI) in CFB [2]		4.12 (-9.55, 17.78)		-0.76 (-3.77, 2.24)	
p-value [3]		0.517		0.617	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	42.90 (5.724)	39.59 (11.084)	39.42 (11.266)	41.57 (12.323)	
Median	46.20	46.20	36.29	46.20	
Min, Max	36.3, 46.2	26.4, 56.1	16.5, 56.1	16.5, 56.1	
C4D1 CFB					
n	3	9	53	116	
LS Mean (StdErr) [2]	10.53 (9.054)	7.13 (6.790)	1.60 (1.568)	3.40 (1.154)	
95% CI [2]	-10.34, 31.41	-8.53, 22.78	-1.50, 4.69	1.12, 5.68	
Difference (95% CI) in CFB [2]		-3.41 (-27.33, 20.51)		1.81 (-1.53, 5.15)	
p-value [3]		0.751		0.287	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	117	
Mean (StdDev)	46.20 (11.448)	43.72 (11.550)	39.26 (11.872)	43.06 (11.977)	
Median	46.20	41.24	36.29	46.20	
Min, Max	36.3, 56.1	26.4, 56.1	16.5, 56.1	16.5, 56.1	
C5D1 CFB					
n	4	8	57	111	
LS Mean (StdErr) [2]	8.77 (5.703)	11.06 (5.703)	1.34 (1.631)	5.07 (1.229)	
95% CI [2]	-4.38, 21.92	-2.09, 24.21	-1.88, 4.56	2.65, 7.50	
Difference (95% CI) in CFB [2]		2.29 (-14.53, 19.11)		3.73 (0.23, 7.23)	
p-value [3]		0.762		0.037	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	38.76 (4.957)	41.79 (12.254)	39.19 (11.892)	42.73 (12.033)	
Median	36.29	46.20	36.29	46.20	
Min, Max	36.3, 46.2	16.5, 56.1	16.5, 56.1	16.5, 56.1	
C6D1 CFB					
n	4	9	55	114	
LS Mean (StdErr) [2]	0.54 (6.319)	9.38 (6.319)	1.47 (1.656)	4.36 (1.216)	
95% CI [2]	-13.76, 14.83	-4.92, 23.67	-1.80, 4.74	1.96, 6.76	
Difference (95% CI) in CFB [2]		8.84 (-9.39, 27.06)		2.90 (-0.67, 6.46)	
p-value [3]		0.301		0.110	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Social Functioning T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	41.24 (9.914)	48.68 (7.010)	40.56 (12.051)	42.37 (12.454)	
Median	36.29	46.20	36.29	46.20	
Min, Max	36.3, 56.1	36.3, 56.1	16.5, 56.1	16.5, 56.1	
C7D1 CFB					
n	4	8	55	113	
LS Mean (StdErr) [2]	2.16 (6.810)	14.36 (6.810)	1.93 (1.675)	3.91 (1.237)	
95% CI [2]	-13.54, 17.87	-1.34, 30.07	-1.38, 5.23	1.47, 6.35	
Difference (95% CI) in CFB [2]		12.20 (-7.89, 32.29)		1.99 (-1.56, 5.53)	
Hedges'G (95% CI) in CFB		0.63 (-0.61, 2.20)		0.15 (-0.17, 0.48)	
p-value [3]		0.199		0.270	
					0.282

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	63	125	
Mean (StdDev)	35.13 (14.515)	37.62 (11.053)	37.61 (11.880)	38.26 (11.882)	
Median	30.99	36.51	33.75	39.27	
Min, Max	22.7, 55.8	22.7, 55.8	11.7, 55.8	11.7, 55.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	39.27 (7.805)	39.27 (12.477)	40.21 (11.526)	41.79 (11.630)	
Median	36.51	42.03	39.27	44.79	
Min, Max	33.8, 50.3	22.7, 55.8	17.2, 55.8	11.7, 55.8	
C2D1 CFB					
n	4	10	61	122	
LS Mean (StdErr) [2]	3.78 (4.539)	3.58 (4.539)	3.22 (1.315)	4.23 (0.992)	
95% CI [2]	-6.33, 13.90	-6.54, 13.69	0.63, 5.82	2.28, 6.19	
Difference (95% CI) in CFB [2]		-0.21 (-13.07, 12.65)		1.01 (-1.82, 3.85)	
p-value [3]		0.972		0.481	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	118	
Mean (StdDev)	40.65 (12.237)	43.13 (14.022)	41.11 (12.499)	41.80 (11.716)	
Median	39.27	47.55	44.79	44.79	
Min, Max	28.2, 55.8	17.2, 55.8	11.7, 55.8	11.7, 55.8	
C3D1 CFB					
n	4	10	59	115	
LS Mean (StdErr) [2]	6.66 (6.156)	9.89 (6.156)	3.65 (1.379)	4.44 (1.028)	
95% CI [2]	-7.05, 20.38	-3.82, 23.61	0.93, 6.38	2.41, 6.47	
Difference (95% CI) in CFB [2]		3.23 (-14.22, 20.67)		0.79 (-2.20, 3.77)	
p-value [3]		0.689		0.603	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	119	
Mean (StdDev)	37.43 (6.373)	42.34 (10.727)	39.66 (12.246)	42.70 (11.980)	
Median	33.75	44.79	39.27	44.79	
Min, Max	33.8, 44.8	22.7, 55.8	17.2, 55.8	11.7, 55.8	
C4D1 CFB					
n	3	9	53	115	
LS Mean (StdErr) [2]	15.52 (7.280)	8.11 (5.460)	2.45 (1.590)	4.81 (1.171)	
95% CI [2]	-1.27, 32.31	-4.49, 20.70	-0.69, 5.59	2.50, 7.12	
Difference (95% CI) in CFB [2]		-7.42 (-26.65, 11.82)		2.36 (-1.03, 5.75)	
p-value [3]		0.400		0.171	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	117	
Mean (StdDev)	42.03 (10.568)	44.10 (9.977)	41.02 (12.298)	43.09 (11.214)	
Median	39.27	44.79	42.03	44.79	
Min, Max	33.8, 55.8	22.7, 55.8	11.7, 55.8	11.7, 55.8	
C5D1 CFB					
n	4	8	57	111	
LS Mean (StdErr) [2]	6.16 (6.558)	4.88 (6.558)	3.11 (1.587)	5.00 (1.196)	
95% CI [2]	-8.97, 21.28	-10.24, 20.01	-0.02, 6.24	2.64, 7.36	
Difference (95% CI) in CFB [2]		-1.27 (-20.62, 18.07)		1.89 (-1.51, 5.30)	
p-value [3]		0.883		0.274	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	58	120	
Mean (StdDev)	40.65 (8.278)	44.18 (12.779)	41.17 (13.140)	42.35 (11.708)	
Median	39.27	50.31	44.79	44.79	
Min, Max	33.8, 50.3	22.7, 55.8	11.7, 55.8	11.7, 55.8	
C6D1 CFB					
n	4	9	55	114	
LS Mean (StdErr) [2]	6.30 (7.955)	10.26 (7.955)	3.00 (1.677)	3.90 (1.231)	
95% CI [2]	-11.70, 24.29	-7.74, 28.25	-0.31, 6.31	1.46, 6.33	
Difference (95% CI) in CFB [2]		3.96 (-18.99, 26.90)		0.90 (-2.71, 4.50)	
p-value [3]		0.705		0.625	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Role Emotional T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	39.27 (6.373)	42.72 (8.311)	40.51 (13.078)	42.66 (11.809)	
Median	39.27	44.79	39.27	44.79	
Min, Max	33.8, 44.8	28.2, 55.8	11.7, 55.8	11.7, 55.8	
C7D1 CFB					
n	4	8	55	113	
LS Mean (StdErr) [2]	3.11 (4.581)	6.08 (4.581)	0.87 (1.545)	3.67 (1.140)	
95% CI [2]	-7.45, 13.68	-4.48, 16.65	-2.18, 3.92	1.42, 5.92	
Difference (95% CI) in CFB [2]		2.97 (-10.54, 16.48)		2.80 (-0.47, 6.06)	
Hedges'G (95% CI) in CFB		0.23 (-1.08, 1.66)		0.23 (-0.09, 0.56)	
p-value [3]		0.626		0.093	
					0.771

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	63	125	
Mean (StdDev)	42.64 (10.536)	37.16 (8.698)	41.33 (9.737)	40.03 (10.283)	
Median	39.59	39.59	39.59	39.59	
Min, Max	33.5, 57.8	21.3, 51.8	21.3, 63.9	15.3, 63.9	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	48.72 (7.853)	40.81 (11.754)	41.84 (10.513)	41.80 (10.387)	
Median	48.72	42.64	39.59	39.59	
Min, Max	39.6, 57.8	15.3, 57.8	21.3, 63.9	15.3, 63.9	
C2D1 CFB					
n	4	10	61	122	
LS Mean (StdErr) [2]	6.04 (3.268)	4.09 (3.268)	0.80 (1.022)	2.41 (0.771)	
95% CI [2]	-1.24, 13.33	-3.19, 11.38	-1.22, 2.81	0.89, 3.93	
Difference (95% CI) in CFB [2]		-1.95 (-11.21, 7.31)		1.62 (-0.58, 3.82)	
p-value [3]		0.649		0.149	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	118	
Mean (StdDev)	45.68 (7.024)	43.24 (11.542)	42.78 (10.528)	43.62 (11.027)	
Median	45.68	45.68	45.68	45.68	
Min, Max	39.6, 51.8	21.3, 57.8	15.3, 63.9	15.3, 63.9	
C3D1 CFB					
n	4	10	59	115	
LS Mean (StdErr) [2]	3.21 (4.180)	8.95 (4.180)	1.27 (1.217)	3.97 (0.907)	
95% CI [2]	-6.10, 12.53	-0.36, 18.27	-1.13, 3.68	2.18, 5.76	
Difference (95% CI) in CFB [2]		5.74 (-6.11, 17.58)		2.70 (0.07, 5.33)	
p-value [3]		0.306		0.045	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	120	
Mean (StdDev)	39.59 (6.083)	45.00 (10.290)	42.90 (10.027)	44.26 (10.948)	
Median	39.59	45.68	39.59	45.68	
Min, Max	33.5, 45.7	27.4, 57.8	21.3, 63.9	15.3, 63.9	
C4D1 CFB					
n	3	9	53	116	
LS Mean (StdErr) [2]	4.94 (5.178)	12.74 (3.884)	2.20 (1.328)	5.05 (0.977)	
95% CI [2]	-7.00, 16.88	3.78, 21.69	-0.42, 4.82	3.12, 6.98	
Difference (95% CI) in CFB [2]		7.79 (-5.89, 21.47)		2.84 (0.01, 5.67)	
p-value [3]		0.225		0.049	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	117	
Mean (StdDev)	41.12 (7.654)	46.44 (6.850)	43.14 (11.160)	43.70 (10.561)	
Median	39.59	45.68	39.59	45.68	
Min, Max	33.5, 51.8	33.5, 57.8	21.3, 63.9	15.3, 63.9	
C5D1 CFB					
n	4	8	57	111	
LS Mean (StdErr) [2]	-1.56 (5.186)	9.67 (5.186)	1.77 (1.324)	3.98 (0.998)	
95% CI [2]	-13.52, 10.40	-2.29, 21.63	-0.84, 4.38	2.01, 5.95	
Difference (95% CI) in CFB [2]		11.23 (-4.07, 26.53)		2.21 (-0.63, 5.05)	
p-value [3]		0.129		0.127	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	57	120	
Mean (StdDev)	45.68 (8.603)	43.65 (10.088)	42.90 (10.092)	43.55 (10.803)	
Median	42.64	45.68	39.59	45.68	
Min, Max	39.6, 57.8	21.3, 57.8	27.4, 63.9	15.3, 63.9	
C6D1 CFB					
n	4	9	54	114	
LS Mean (StdErr) [2]	4.85 (3.859)	9.35 (3.859)	1.18 (1.339)	4.10 (0.979)	
95% CI [2]	-3.88, 13.58	0.62, 18.07	-1.47, 3.82	2.17, 6.03	
Difference (95% CI) in CFB [2]		4.50 (-6.63, 15.63)		2.92 (0.04, 5.81)	
p-value [3]		0.385		0.047	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Health T-Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	45.68 (4.967)	45.68 (9.755)	42.85 (11.235)	43.89 (11.836)	
Median	45.68	45.68	45.68	45.68	
Min, Max	39.6, 51.8	33.5, 57.8	15.3, 63.9	15.3, 63.9	
C7D1 CFB					
n	4	8	55	113	
LS Mean (StdErr) [2]	3.43 (4.098)	12.79 (4.098)	1.22 (1.554)	4.06 (1.147)	
95% CI [2]	-6.02, 12.88	3.34, 22.24	-1.84, 4.29	1.80, 6.33	
Difference (95% CI) in CFB [2]		9.36 (-2.73, 21.45)		2.84 (-0.45, 6.13)	
Hedges'G (95% CI) in CFB		0.81 (-0.42, 2.44)		0.24 (-0.09, 0.56)	
p-value [3]		0.112		0.090	
					0.823

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	63	124	
Mean (StdDev)	40.04 (12.729)	29.95 (12.719)	33.69 (10.566)	34.14 (10.613)	
Median	38.42	25.43	32.30	33.47	
Min, Max	27.1, 56.2	17.1, 50.2	13.8, 60.4	10.5, 61.8	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	41.70 (12.441)	33.63 (13.953)	36.26 (10.870)	38.05 (11.924)	
Median	37.34	27.99	35.38	39.19	
Min, Max	32.1, 60.0	15.0, 51.1	16.5, 61.2	13.0, 58.5	
C2D1 CFB					
n	4	10	61	121	
LS Mean (StdErr) [2]	1.46 (3.060)	3.74 (3.060)	1.00 (0.984)	2.41 (0.749)	
95% CI [2]	-5.36, 8.28	-3.08, 10.55	-0.94, 2.94	0.93, 3.89	
Difference (95% CI) in CFB [2]		2.28 (-6.40, 10.95)		1.41 (-0.71, 3.53)	
p-value [3]		0.572		0.190	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	118	
Mean (StdDev)	44.58 (10.667)	35.92 (14.634)	35.64 (10.026)	39.01 (11.950)	
Median	41.47	34.14	34.87	39.70	
Min, Max	35.4, 60.0	15.8, 58.0	15.1, 62.6	13.3, 61.4	
C3D1 CFB					
n	4	10	59	114	
LS Mean (StdErr) [2]	3.63 (3.988)	5.51 (3.988)	1.37 (0.992)	4.36 (0.747)	
95% CI [2]	-5.25, 12.52	-3.37, 14.40	-0.59, 3.33	2.88, 5.83	
Difference (95% CI) in CFB [2]		1.88 (-9.42, 13.19)		2.99 (0.84, 5.13)	
p-value [3]		0.718		0.007	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	117	
Mean (StdDev)	43.41 (11.346)	38.84 (14.698)	36.28 (10.546)	39.01 (11.436)	
Median	37.50	43.72	36.16	40.52	
Min, Max	36.2, 56.5	18.1, 59.8	10.8, 61.5	12.8, 59.1	
C4D1 CFB					
n	3	9	53	112	
LS Mean (StdErr) [2]	7.99 (5.573)	8.59 (4.180)	1.68 (1.130)	3.76 (0.862)	
95% CI [2]	-4.86, 20.84	-1.05, 18.23	-0.55, 3.91	2.06, 5.47	
Difference (95% CI) in CFB [2]		0.60 (-14.12, 15.32)		2.09 (-0.32, 4.49)	
p-value [3]		0.928		0.089	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	117	
Mean (StdDev)	46.18 (7.218)	35.48 (16.463)	36.01 (11.142)	39.13 (11.821)	
Median	47.89	37.68	36.65	38.81	
Min, Max	36.0, 52.9	15.4, 57.1	13.5, 60.1	13.0, 64.3	
C5D1 CFB					
n	4	8	57	110	
LS Mean (StdErr) [2]	7.66 (5.104)	7.64 (5.104)	1.26 (1.088)	4.30 (0.827)	
95% CI [2]	-4.11, 19.43	-4.13, 19.41	-0.89, 3.41	2.67, 5.94	
Difference (95% CI) in CFB [2]		-0.02 (-15.07, 15.04)		3.04 (0.71, 5.38)	
p-value [3]		0.998		0.011	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	57	120	
Mean (StdDev)	44.18 (9.625)	39.09 (14.725)	35.10 (11.019)	40.55 (11.709)	
Median	41.27	46.60	33.16	41.48	
Min, Max	36.0, 58.1	17.3, 54.8	16.4, 58.8	17.5, 61.0	
C6D1 CFB					
n	4	9	54	113	
LS Mean (StdErr) [2]	3.59 (5.483)	7.09 (5.483)	0.45 (1.132)	5.39 (0.836)	
95% CI [2]	-8.81, 16.00	-5.32, 19.49	-1.79, 2.69	3.74, 7.04	
Difference (95% CI) in CFB [2]		3.49 (-12.32, 19.31)		4.94 (2.50, 7.38)	
p-value [3]		0.629		<0.0001	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Physical Component Summary (PCS) Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	44.46 (8.956)	42.33 (14.936)	37.03 (10.981)	39.71 (12.104)	
Median	42.37	45.21	36.89	39.40	
Min, Max	36.0, 57.1	17.0, 56.2	14.5, 63.2	12.5, 63.1	
C7D1 CFB					
n	4	8	55	112	
LS Mean (StdErr) [2]	4.72 (4.869)	10.77 (4.869)	1.37 (1.194)	3.79 (0.891)	
95% CI [2]	-6.51, 15.95	-0.46, 22.00	-0.99, 3.72	2.03, 5.55	
Difference (95% CI) in CFB [2]		6.05 (-8.31, 20.41)		2.42 (-0.10, 4.95)	
Hedges'G (95% CI) in CFB		0.44 (-0.83, 1.93)		0.26 (-0.06, 0.59)	
p-value [3]		0.360		0.060	
					0.611

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
Baseline					
n	4	10	63	124	
Mean (StdDev)	39.76 (13.173)	38.54 (10.126)	41.07 (10.610)	40.76 (10.564)	
Median	36.58	35.68	39.84	41.90	
Min, Max	27.7, 58.2	26.2, 61.0	19.2, 63.9	13.2, 64.0	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C2D1					
n	4	10	65	127	
Mean (StdDev)	43.72 (8.656)	41.02 (11.539)	42.50 (11.089)	42.67 (10.336)	
Median	46.30	42.00	42.35	42.79	
Min, Max	31.4, 50.9	19.6, 64.8	19.9, 64.4	19.0, 63.4	
C2D1 CFB					
n	4	10	61	121	
LS Mean (StdErr) [2]	3.60 (3.441)	4.50 (3.441)	1.97 (1.124)	2.92 (0.856)	
95% CI [2]	-4.06, 11.27	-3.16, 12.17	-0.25, 4.18	1.23, 4.61	
Difference (95% CI) in CFB [2]		0.90 (-8.85, 10.65)		0.96 (-1.46, 3.38)	
p-value [3]		0.841		0.437	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C3D1					
n	4	10	63	118	
Mean (StdDev)	41.56 (9.589)	44.19 (10.282)	43.94 (10.955)	43.27 (10.630)	
Median	42.52	45.94	44.18	45.29	
Min, Max	31.4, 49.9	21.4, 58.3	11.2, 63.3	13.8, 66.0	
C3D1 CFB					
n	4	10	59	114	
LS Mean (StdErr) [2]	2.48 (4.622)	10.48 (4.622)	3.01 (1.150)	3.27 (0.865)	
95% CI [2]	-7.82, 12.77	0.18, 20.78	0.73, 5.28	1.57, 4.98	
Difference (95% CI) in CFB [2]		8.00 (-5.10, 21.10)		0.27 (-2.22, 2.76)	
p-value [3]		0.203		0.831	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C4D1					
n	3	9	57	117	
Mean (StdDev)	40.23 (9.412)	44.26 (9.919)	42.45 (10.168)	44.30 (10.870)	
Median	42.33	45.70	41.05	44.94	
Min, Max	29.9, 48.4	26.1, 60.6	22.0, 59.7	13.7, 63.9	
C4D1 CFB					
n	3	9	53	112	
LS Mean (StdErr) [2]	11.41 (5.637)	10.16 (4.228)	1.70 (1.385)	4.04 (1.056)	
95% CI [2]	-1.59, 24.41	0.42, 19.91	-1.03, 4.44	1.95, 6.13	
Difference (95% CI) in CFB [2]		-1.25 (-16.14, 13.65)		2.34 (-0.61, 5.28)	
p-value [3]		0.852		0.119	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C5D1					
n	4	8	60	117	
Mean (StdDev)	42.93 (9.972)	47.68 (7.924)	43.16 (11.811)	44.42 (10.653)	
Median	43.34	48.50	44.14	45.71	
Min, Max	31.9, 53.2	39.1, 61.7	14.1, 61.6	19.5, 64.4	
C5D1 CFB					
n	4	8	57	110	
LS Mean (StdErr) [2]	2.84 (4.930)	9.35 (4.930)	2.10 (1.433)	4.14 (1.090)	
95% CI [2]	-8.53, 14.20	-2.02, 20.72	-0.73, 4.93	1.99, 6.30	
Difference (95% CI) in CFB [2]		6.52 (-8.03, 21.06)		2.04 (-1.03, 5.12)	
p-value [3]		0.332		0.191	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C6D1					
n	4	9	57	120	
Mean (StdDev)	41.82 (10.250)	45.00 (9.711)	43.47 (10.650)	43.78 (10.981)	
Median	42.78	44.46	42.30	45.74	
Min, Max	29.6, 52.1	26.1, 58.5	24.1, 61.4	12.1, 61.5	
C6D1 CFB					
n	4	9	54	113	
LS Mean (StdErr) [2]	3.49 (6.382)	10.59 (6.382)	2.07 (1.395)	3.35 (1.029)	
95% CI [2]	-10.95, 17.92	-3.84, 25.03	-0.68, 4.83	1.32, 5.39	
Difference (95% CI) in CFB [2]		7.11 (-11.30, 25.52)		1.28 (-1.73, 4.29)	
p-value [3]		0.405		0.401	

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 35.2.10.1.8a
Change from Baseline of SF-12 by Prior TKI Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

Mental Component Summary (MCS) Score

	Prior TKI therapy = Yes		Prior TKI therapy = No		
	Placebo (N=4)	Avapritinib 25 mg (N=10)	Placebo (N=67)	Avapritinib 25 mg (N=131)	Test of Interaction p-value [1]
C7D1					
n	4	8	58	119	
Mean (StdDev)	43.24 (9.147)	46.76 (7.708)	43.13 (11.689)	44.08 (11.545)	
Median	41.50	45.15	43.12	45.10	
Min, Max	34.9, 55.1	38.0, 60.6	12.1, 64.9	12.0, 63.3	
C7D1 CFB					
n	4	8	55	112	
LS Mean (StdErr) [2]	3.34 (4.393)	11.66 (4.393)	1.43 (1.434)	3.63 (1.070)	
95% CI [2]	-6.79, 13.46	1.54, 21.79	-1.40, 4.26	1.51, 5.74	
Difference (95% CI) in CFB [2]		8.33 (-4.63, 21.29)		2.20 (-0.83, 5.23)	
Hedges'G (95% CI) in CFB		0.67 (-0.57, 2.25)		0.20 (-0.13, 0.53)	
p-value [3]		0.177		0.154	
					0.714

Abbreviations: SF-12 = Twelve-item Short Form Health Survey, CFB = Change From Baseline, LS Mean = Least Squares Mean, CI = Confidence Interval, NA = Not Available, NE = Not Estimable.
Note: Baseline score refers to the last assessment value prior to C1D1 dosing in part 2 of the study.
[1] Two-sided p-values for treatment-by-subgroup interaction are from ANCOVA model with randomization stratification factor (Serum tryptase <20 ng/mL vs. >=20 ng/mL), Baseline ISM status (moderate vs. severe), treatment, subgroup, treatment*subgroup in the model.
[2] Change from baseline summary and difference of mean change from baseline between Avapritinib 25mg and Placebo are from least squares mean estimation of the ANCOVA model that controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
[3] Two-sided p-value from ANCOVA model controlling for randomization stratification factor (tryptase) and Baseline ISM status (moderate vs severe).
Cross References: Listing 16.2.6.2.5
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sf12-g-itt-thpy-a.sas Date: 15:57/07AUG2023

Table 03a
Time to Improvement in Weeks for SF-12
Intent-to-Treat Population
Part 2 Baseline

SF-12 PCS Change from Baseline >= 9.1	Placebo (N=71) n/N (%)	Placebo (N=71) Median in Weeks (95% CIs) [1]	Avapritinib 25 mg (N=141) n/N (%)	Avapritinib 25 mg (N=141) Median in Weeks (95% CIs) [1]	Avapritinib 25 mg vs. Placebo HR [2] (95% CIs) P-Value	Interaction p-value [3]
Overall	25/ 71 (35.2)	27.143 (27.143, NA)	71/141 (50.4)	20.143 (16.143, NA)	1.557 (0.986, 2.460) 0.0575	
Age Group (Years)						0.607
< 65	22/ 60 (36.7)	27.143 (27.143, NA)	66/132 (50.0)	20.286 (16.143, NA)	1.486 (0.916, 2.412) 0.1087	
>= 65	3/ 11 (27.3)	NA (8.143, NA)	5/ 9 (55.6)	19.857 (8.286, NA)	2.077 (0.495, 8.711) 0.3175	
Sex						0.695
Male	5/ 17 (29.4)	27.143 (NA, NA)	19/ 41 (46.3)	NA (16.429, NA)	2.333 (0.793, 6.862) 0.1239	
Female	20/ 54 (37.0)	NA (24.143, NA)	52/100 (52.0)	20.000 (12.143, NA)	1.483 (0.884, 2.488) 0.1357	
Region						0.304
North America	10/ 33 (30.3)	27.143 (NA, NA)	34/ 60 (56.7)	19.286 (8.286, 27.429)	1.963 (0.966, 3.988) 0.0622	
Europe	15/ 38 (39.5)	NA (23.857, NA)	37/ 81 (45.7)	NA (19.143, NA)	1.280 (0.702, 2.333) 0.4199	

Abbreviations: NA = Not Available, HR = Hazard Ratio, CIs = Confidence Limits
Time to improvement is defined as time from first dose date to first time patient reached improvement (as defined in the table). Patients without improvement will be censored at the date of last available data.
[1] Median time to improvement is calculated based on Kaplan-Meier method.
[2] Hazard Ratio (HR) is calculated based on Cox proportional hazards model. HR > 1 correspond to a benefit for Avapritinib.
[3] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-03a-sf12-tte-c7d1-itt.sas Date: 15:37/09AUG2023

Table 03a
Time to Improvement in Weeks for SF-12
Intent-to-Treat Population
Part 2 Baseline

SF-12 PCS Change from Baseline >= 9.1	Placebo (N=71) n/N (%)	Placebo (N=71) Median in Weeks (95% CIs) [1]	Avapritinib 25 mg (N=141) n/N (%)	Avapritinib 25 mg (N=141) Median in Weeks (95% CIs) [1]	Avapritinib 25 mg vs. Placebo HR [2] (95% CIs) P-Value	Interaction p-value [3]
Country						NA
BEL	1/ 1 (100.0)	4.000 (NA, NA)	2/ 3 (66.7)	4.143 (3.857, NA)	NA (NA, NA) NA	
CAN	2/ 5 (40.0)	NA (3.857, NA)	5/ 8 (62.5)	19.857 (4.286, 27.429)	NA (NA, NA) NA	
CHE	0/ 1 (0.0)	NA (NA, NA)	0/ 2 (0.0)	NA (NA, NA)	NA (NA, NA) NA	
DEU	6/ 15 (40.0)	NA (16.143, NA)	6/ 19 (31.6)	NA (20.143, NA)	NA (NA, NA) NA	
DNK	0/ 0	NA (NA, NA)	1/ 1 (100.0)	4.143 (NA, NA)	NA (NA, NA) NA	
ESP	0/ 3 (0.0)	NA (NA, NA)	8/ 14 (57.1)	10.429 (8.143, NA)	NA (NA, NA) NA	
FRA	4/ 6 (66.7)	12.286 (8.143, NA)	6/ 11 (54.5)	20.143 (4.143, NA)	NA (NA, NA) NA	
GBR	0/ 5 (0.0)	NA (NA, NA)	3/ 11 (27.3)	NA (20.143, NA)	NA (NA, NA) NA	
ITA	0/ 0	NA (NA, NA)	2/ 4 (50.0)	NA (4.000, NA)	NA (NA, NA) NA	
NLD	2/ 3 (66.7)	20.143 (12.143, NA)	6/ 9 (66.7)	16.143 (12.143, NA)	NA (NA, NA) NA	
NOR	2/ 3 (66.7)	23.857 (7.714, NA)	2/ 5 (40.0)	NA (12.286, NA)	NA (NA, NA) NA	
SWE	0/ 1 (0.0)	NA (NA, NA)	1/ 2 (50.0)	NA (20.000, NA)	NA (NA, NA) NA	
USA	8/ 28 (28.6)	27.143 (NA, NA)	29/ 52 (55.8)	19.286 (8.286, NA)	NA (NA, NA) NA	

Abbreviations: NA = Not Available, HR = Hazard Ratio, CIs = Confidence Limits
Time to improvement is defined as time from first dose date to first time patient reached improvement (as defined in the table). Patients without improvement will be censored at the date of last available data.
[1] Median time to improvement is calculated based on Kaplan-Meier method.
[2] Hazard Ratio (HR) is calculated based on Cox proportional hazards model. HR > 1 correspond to a benefit for Avapritinib.
[3] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-03a-sf12-tte-c7d1-itt.sas Date: 15:37/09AUG2023

Table 03a
Time to Improvement in Weeks for SF-12
Intent-to-Treat Population
Part 2 Baseline

SF-12 PCS Change from Baseline >= 9.1	Placebo (N=71) n/N (%)	Placebo (N=71) Median in Weeks (95% CIs) [1]	Avapritinib 25 mg (N=141) n/N (%)	Avapritinib 25 mg (N=141) Median in Weeks (95% CIs) [1]	Avapritinib 25 mg vs. Placebo HR [2] (95% CIs) P-Value	Interaction p-value [3]
Baseline ISM Status						0.999
Moderate	7/ 26 (26.9)	NA (NA, NA)	22/ 52 (42.3)	NA (16.143, NA)	1.598 (0.683, 3.741) 0.2799	
Severe	18/ 45 (40.0)	27.143 (23.857, NA)	48/ 87 (55.2)	19.571 (12.143, NA)	1.582 (0.917, 2.729) 0.0990	
Baseline Serum Tryptase (ng/mL)						0.341
< 20	2/ 15 (13.3)	NA (NA, NA)	11/ 28 (39.3)	NA (19.571, NA)	3.067 (0.679, 13.845) 0.1450	
>= 20	23/ 56 (41.1)	27.143 (23.857, NA)	60/113 (53.1)	19.857 (12.143, NA)	1.425 (0.879, 2.308) 0.1505	
ECOG Status						0.460
0 or 1	23/ 67 (34.3)	27.143 (27.143, NA)	66/131 (50.4)	20.143 (16.143, NA)	1.648 (1.024, 2.652) 0.0396	
2+	2/ 4 (50.0)	NA (4.286, NA)	5/ 10 (50.0)	27.429 (12.143, 27.429)	0.804 (0.146, 4.412) 0.8015	
Prior TKI therapy						0.618
Yes	1/ 4 (25.0)	NA (8.571, NA)	5/ 10 (50.0)	12.143 (8.286, NA)	2.605 (0.303, 22.373) 0.3830	
No	24/ 67 (35.8)	27.143 (27.143, NA)	66/131 (50.4)	20.286 (16.143, NA)	1.513 (0.947, 2.418) 0.0831	

Abbreviations: NA = Not Available, HR = Hazard Ratio, CIs = Confidence Limits
Time to improvement is defined as time from first dose date to first time patient reached improvement (as defined in the table). Patients without improvement will be censored at the date of last available data.
[1] Median time to improvement is calculated based on Kaplan-Meier method.
[2] Hazard Ratio (HR) is calculated based on Cox proportional hazards model. HR > 1 correspond to a benefit for Avapritinib.
[3] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-03a-sf12-tte-c7d1-itt.sas Date: 15:37/09AUG2023

Table 03a
Time to Improvement in Weeks for SF-12
Intent-to-Treat Population
Part 2 Baseline

SF-12 MCS Change from Baseline >= 8.5	Placebo (N=71) n/N (%)	Placebo (N=71) Median in Weeks (95% CIs) [1]	Avapritinib 25 mg (N=141) n/N (%)	Avapritinib 25 mg (N=141) Median in Weeks (95% CIs) [1]	Avapritinib 25 mg vs. Placebo HR [2] (95% CIs) P-Value	Inter-action p-value [3]
Overall	30/ 71 (42.3)	NA (20.286, NA)	70/141 (49.6)	24.143 (15.857, NA)	1.195 (0.779, 1.834) 0.4147	
Age Group (Years)						0.188
< 65	27/ 60 (45.0)	24.429 (20.000, NA)	64/132 (48.5)	24.286 (16.143, NA)	1.070 (0.682, 1.678) 0.7695	
>= 65	3/ 11 (27.3)	NA (24.143, NA)	6/ 9 (66.7)	12.143 (8.143, NA)	2.983 (0.733, 12.147) 0.1270	
Sex						0.647
Male	6/ 17 (35.3)	NA (10.143, NA)	15/ 41 (36.6)	NA (24.000, NA)	0.995 (0.386, 2.565) 0.9913	
Female	24/ 54 (44.4)	24.429 (20.000, NA)	55/100 (55.0)	16.286 (12.143, NA)	1.301 (0.805, 2.104) 0.2829	
Region						0.224
North America	11/ 33 (33.3)	NA (24.429, NA)	30/ 60 (50.0)	24.000 (12.143, NA)	1.647 (0.824, 3.290) 0.1579	
Europe	19/ 38 (50.0)	24.143 (12.143, NA)	40/ 81 (49.4)	24.143 (15.143, NA)	0.949 (0.550, 1.639) 0.8515	

Abbreviations: NA = Not Available, HR = Hazard Ratio, CIs = Confidence Limits
Time to improvement is defined as time from first dose date to first time patient reached improvement (as defined in the table). Patients without improvement will be censored at the date of last available data.
[1] Median time to improvement is calculated based on Kaplan-Meier method.
[2] Hazard Ratio (HR) is calculated based on Cox proportional hazards model. HR > 1 correspond to a benefit for Avapritinib.
[3] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-03a-sf12-tte-c7d1-itt.sas Date: 15:37/09AUG2023

Table 03a
Time to Improvement in Weeks for SF-12
Intent-to-Treat Population
Part 2 Baseline

SF-12 MCS Change from Baseline >= 8.5	Placebo (N=71) n/N (%)	Placebo (N=71) Median in Weeks (95% CIs) [1]	Avapritinib 25 mg (N=141) n/N (%)	Avapritinib 25 mg (N=141) Median in Weeks (95% CIs) [1]	Avapritinib 25 mg vs. Placebo HR [2] (95% CIs) P-Value	Interaction p-value [3]
Country						NA
BEL	1/ 1 (100.0)	8.000 (NA, NA)	0/ 3 (0.0)	NA (NA, NA)	NA (NA, NA) NA	
CAN	0/ 5 (0.0)	NA (NA, NA)	5/ 8 (62.5)	11.571 (8.143, NA)	NA (NA, NA) NA	
CHE	1/ 1 (100.0)	4.286 (NA, NA)	0/ 2 (0.0)	NA (NA, NA)	NA (NA, NA) NA	
DEU	9/ 15 (60.0)	12.143 (4.143, NA)	7/ 19 (36.8)	NA (16.571, NA)	NA (NA, NA) NA	
DNK	0/ 0	NA (NA, NA)	1/ 1 (100.0)	17.143 (NA, NA)	NA (NA, NA) NA	
ESP	0/ 3 (0.0)	NA (NA, NA)	4/ 14 (28.6)	NA (20.286, NA)	NA (NA, NA) NA	
FRA	4/ 6 (66.7)	22.071 (16.286, NA)	7/ 11 (63.6)	8.714 (4.143, NA)	NA (NA, NA) NA	
GBR	3/ 5 (60.0)	8.143 (4.143, NA)	6/ 11 (54.5)	11.857 (8.143, NA)	NA (NA, NA) NA	
ITA	0/ 0	NA (NA, NA)	3/ 4 (75.0)	12.214 (4.000, NA)	NA (NA, NA) NA	
NLD	1/ 3 (33.3)	NA (20.143, NA)	8/ 9 (88.9)	12.143 (4.429, 12.143)	NA (NA, NA) NA	
NOR	0/ 3 (0.0)	NA (NA, NA)	3/ 5 (60.0)	12.143 (4.143, NA)	NA (NA, NA) NA	
SWE	0/ 1 (0.0)	NA (NA, NA)	1/ 2 (50.0)	NA (8.286, NA)	NA (NA, NA) NA	
USA	11/ 28 (39.3)	NA (16.286, NA)	25/ 52 (48.1)	24.286 (12.143, NA)	NA (NA, NA) NA	

Abbreviations: NA = Not Available, HR = Hazard Ratio, CIs = Confidence Limits
Time to improvement is defined as time from first dose date to first time patient reached improvement (as defined in the table). Patients without improvement will be censored at the date of last available data.
[1] Median time to improvement is calculated based on Kaplan-Meier method.
[2] Hazard Ratio (HR) is calculated based on Cox proportional hazards model. HR > 1 correspond to a benefit for Avapritinib.
[3] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-03a-sf12-tte-c7d1-itt.sas Date: 15:37/09AUG2023

Table 03a
Time to Improvement in Weeks for SF-12
Intent-to-Treat Population
Part 2 Baseline

SF-12 MCS Change from Baseline >= 8.5	Placebo (N=71) n/N (%)	Placebo (N=71) Median in Weeks (95% CIs) [1]	Avapritinib 25 mg (N=141) n/N (%)	Avapritinib 25 mg (N=141) Median in Weeks (95% CIs) [1]	Avapritinib 25 mg vs. Placebo HR [2] (95% CIs) P-Value	Inter-action p-value [3]
Baseline ISM Status						0.089
Moderate	5/ 26 (19.2)	NA (NA, NA)	22/ 52 (42.3)	NA (15.143, NA)	2.334 (0.883, 6.166) 0.0873	
Severe	25/ 45 (55.6)	20.143 (10.143, NA)	47/ 87 (54.0)	16.571 (12.143, NA)	0.951 (0.585, 1.546) 0.8380	
Baseline Serum Tryptase (ng/mL)						0.768
< 20	7/ 15 (46.7)	24.429 (8.000, NA)	16/ 28 (57.1)	16.214 (7.714, NA)	1.340 (0.549, 3.273) 0.5201	
>= 20	23/ 56 (41.1)	NA (20.000, NA)	54/113 (47.8)	24.286 (16.143, NA)	1.152 (0.707, 1.877) 0.5704	
ECOG Status						0.208
0 or 1	27/ 67 (40.3)	NA (20.857, NA)	65/131 (49.6)	24.143 (16.143, NA)	1.276 (0.814, 1.999) 0.2884	
2+	3/ 4 (75.0)	6.214 (4.143, NA)	5/ 10 (50.0)	NA (8.143, NA)	0.491 (0.116, 2.082) 0.3342	
Prior TKI therapy						0.907
Yes	2/ 4 (50.0)	NA (4.143, NA)	6/ 10 (60.0)	8.714 (8.143, NA)	1.045 (0.209, 5.224) 0.9568	
No	28/ 67 (41.8)	NA (20.286, NA)	64/131 (48.9)	24.286 (16.143, NA)	1.184 (0.759, 1.847) 0.4563	

Abbreviations: NA = Not Available, HR = Hazard Ratio, CIs = Confidence Limits
Time to improvement is defined as time from first dose date to first time patient reached improvement (as defined in the table). Patients without improvement will be censored at the date of last available data.
[1] Median time to improvement is calculated based on Kaplan-Meier method.
[2] Hazard Ratio (HR) is calculated based on Cox proportional hazards model. HR > 1 correspond to a benefit for Avapritinib.
[3] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-03a-sf12-tte-c7d1-itt.sas Date: 15:37/09AUG2023

Table 35.3.1.1.1.1a
Summary of All Adverse Events by Age Group
Safety Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Overall	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [3]
Any AEs, n (%)	55 (91.7)	120 (90.9)	11 (100.0)	8 (88.9)	0.948
Odds Ratio (95% CIs) [1], P-Value		0.909 (0.305, 2.707), 0.864		NE (NE, NE), 0.257	
Relative Risk (95% CIs) [2], P-Value		0.992 (0.903, 1.089), 0.862		0.889 (0.706, 1.120), 0.318	
Risk Difference (95% CIs) [2], P-Value		-0.008 (-0.093, 0.078), 0.862		-0.111 (-0.316, 0.094), 0.289	
AEs Related to Study Drug, n (%)	28 (46.7)	69 (52.3)	4 (36.4)	8 (88.9)	0.057
Odds Ratio (95% CIs) [1], P-Value		1.252 (0.679, 2.307), 0.471		14.000 (1.252, 156.610), 0.017	
Relative Risk (95% CIs) [2], P-Value		1.120 (0.817, 1.536), 0.481		2.444 (1.082, 5.523), 0.032	
Risk Difference (95% CIs) [2], P-Value		0.056 (-0.096, 0.208), 0.471		0.525 (0.175, 0.876), 0.003	
Serious AEs, n (%)	6 (10.0)	6 (4.5)	2 (18.2)	1 (11.1)	0.851
Odds Ratio (95% CIs) [1], P-Value		0.429 (0.132, 1.389), 0.148		0.563 (0.043, 7.442), 0.660	
Relative Risk (95% CIs) [2], P-Value		0.455 (0.153, 1.351), 0.156		0.611 (0.066, 5.700), 0.666	
Risk Difference (95% CIs) [2], P-Value		-0.055 (-0.138, 0.029), 0.202		-0.071 (-0.377, 0.236), 0.651	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.1a
Summary of All Adverse Events by Age Group
Safety Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Overall	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [3]
Grade 1-2 AEs, n (%)	54 (90.0)	119 (90.2)	11 (100.0)	8 (88.9)	0.945
Odds Ratio (95% CIs) [1], P-Value		1.017 (0.367, 2.819), 0.974		NE (NE, NE), 0.257	
Relative Risk (95% CIs) [2], P-Value		1.002 (0.905, 1.109), 0.974		0.889 (0.706, 1.120), 0.318	
Risk Difference (95% CIs) [2], P-Value		0.002 (-0.090, 0.093), 0.974		-0.111 (-0.316, 0.094), 0.289	
Grade 1-2 AEs Related to Study Drug, n (%)	28 (46.7)	69 (52.3)	4 (36.4)	8 (88.9)	0.057
Odds Ratio (95% CIs) [1], P-Value		1.252 (0.679, 2.307), 0.471		14.000 (1.252, 156.610), 0.017	
Relative Risk (95% CIs) [2], P-Value		1.120 (0.817, 1.536), 0.481		2.444 (1.082, 5.523), 0.032	
Risk Difference (95% CIs) [2], P-Value		0.056 (-0.096, 0.208), 0.471		0.525 (0.175, 0.876), 0.003	
Grade >=3 AEs, n (%)	13 (21.7)	29 (22.0)	2 (18.2)	1 (11.1)	0.665
Odds Ratio (95% CIs) [1], P-Value		1.018 (0.486, 2.133), 0.962		0.563 (0.043, 7.442), 0.660	
Relative Risk (95% CIs) [2], P-Value		1.014 (0.568, 1.809), 0.962		0.611 (0.066, 5.700), 0.666	
Risk Difference (95% CIs) [2], P-Value		0.003 (-0.123, 0.129), 0.962		-0.071 (-0.377, 0.236), 0.651	
Grade >=3 AEs Related to Study Drug, n (%)	2 (3.3)	2 (1.5)	0	1 (11.1)	0.943
Odds Ratio (95% CIs) [1], P-Value		0.446 (0.061, 3.245), 0.414		NE (NE, NE), 0.257	
Relative Risk (95% CIs) [2], P-Value		0.455 (0.066, 3.151), 0.425		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.018 (-0.068, 0.032), 0.476		0.111 (-0.094, 0.316), 0.289	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.1a
Summary of All Adverse Events by Age Group
Safety Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Overall	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	7 (11.7)	11 (8.3)	2 (18.2)	1 (11.1)	0.886
Odds Ratio (95% CIs) [1], P-Value		0.688 (0.253, 1.873), 0.463		0.563 (0.043, 7.442), 0.660	
Relative Risk (95% CIs) [2], P-Value		0.714 (0.291, 1.752), 0.462		0.611 (0.066, 5.700), 0.666	
Risk Difference (95% CIs) [2], P-Value		-0.033 (-0.127, 0.061), 0.487		-0.071 (-0.377, 0.236), 0.651	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	1 (1.7)	2 (1.5)	0	0	>0.999
Odds Ratio (95% CIs) [1], P-Value		0.908 (0.081, 10.209), 0.937		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.909 (0.084, 9.832), 0.937		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.002 (-0.040, 0.037), 0.939		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	1 (1.7)	2 (1.5)	0	1 (11.1)	0.951
Odds Ratio (95% CIs) [1], P-Value		0.908 (0.081, 10.209), 0.937		NE (NE, NE), 0.257	
Relative Risk (95% CIs) [2], P-Value		0.909 (0.084, 9.832), 0.937		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.002 (-0.040, 0.037), 0.939		0.111 (-0.094, 0.316), 0.289	
Related AEs Leading to Interruption of Study Drug, n (%)	3 (5.0)	5 (3.8)	1 (9.1)	0	0.948
Odds Ratio (95% CIs) [1], P-Value		0.748 (0.173, 3.237), 0.697		NE (NE, NE), 0.353	
Relative Risk (95% CIs) [2], P-Value		0.758 (0.187, 3.067), 0.697		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.012 (-0.076, 0.052), 0.711		-0.091 (-0.261, 0.079), 0.294	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.1a
Summary of All Adverse Events by Age Group
Safety Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Overall	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	1 (1.7)	1 (0.8)	0	0	0.997
Odds Ratio (95% CIs) [1], P-Value		0.450 (0.028, 7.324), 0.565		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.455 (0.029, 7.146), 0.575		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.009 (-0.045, 0.027), 0.617		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	1 (1.7)	2 (1.5)	0	0	>0.999
Odds Ratio (95% CIs) [1], P-Value		0.908 (0.081, 10.209), 0.937		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.909 (0.084, 9.832), 0.937		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.002 (-0.040, 0.037), 0.939		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.1a
Summary of All Adverse Events by Age Group
Safety Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Cognitive Effects AESI	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [3]
Any AEs, n (%)	2 (3.3)	4 (3.0)	1 (9.1)	0	0.952
Odds Ratio (95% CIs) [1], P-Value		0.906 (0.161, 5.089), 0.911		NE (NE, NE), 0.353	
Relative Risk (95% CIs) [2], P-Value		0.909 (0.171, 4.828), 0.911		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.003 (-0.057, 0.051), 0.912		-0.091 (-0.261, 0.079), 0.294	
AEs Related to Study Drug, n (%)	2 (3.3)	3 (2.3)	0	0	0.998
Odds Ratio (95% CIs) [1], P-Value		0.674 (0.110, 4.145), 0.669		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.682 (0.117, 3.975), 0.670		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.011 (-0.063, 0.041), 0.690		NA (NA, NA), NA	
Serious AEs, n (%)	0	0	1 (9.1)	0	0.965
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.353	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.091 (-0.261, 0.079), 0.294	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.1a
Summary of All Adverse Events by Age Group
Safety Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Cognitive Effects AESI	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [3]
Grade 1-2 AEs, n (%)	2 (3.3)	4 (3.0)	0	0	>0.999
Odds Ratio (95% CIs) [1], P-Value		0.906 (0.161, 5.089), 0.911		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.909 (0.171, 4.828), 0.911		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.003 (-0.057, 0.051), 0.912		NA (NA, NA), NA	
Grade 1-2 AEs Related to Study Drug, n (%)	2 (3.3)	3 (2.3)	0	0	0.998
Odds Ratio (95% CIs) [1], P-Value		0.674 (0.110, 4.145), 0.669		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.682 (0.117, 3.975), 0.670		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.011 (-0.063, 0.041), 0.690		NA (NA, NA), NA	
Grade >=3 AEs, n (%)	0	0	1 (9.1)	0	0.965
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.353	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.091 (-0.261, 0.079), 0.294	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.1a
Summary of All Adverse Events by Age Group
Safety Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Cognitive Effects AESI	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	2 (1.5)	0	0	0.974
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.338		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.015 (-0.006, 0.036), 0.154		NA (NA, NA), NA	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	1 (1.7)	1 (0.8)	0	0	0.997
Odds Ratio (95% CIs) [1], P-Value		0.450 (0.028, 7.324), 0.565		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.455 (0.029, 7.146), 0.575		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.009 (-0.045, 0.027), 0.617		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	2 (1.5)	0	0	0.974
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.338		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.015 (-0.006, 0.036), 0.154		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.1a
Summary of All Adverse Events by Age Group
Safety Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Cognitive Effects AESI	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	1 (1.7)	1 (0.8)	0	0	0.997
Odds Ratio (95% CIs) [1], P-Value		0.450 (0.028, 7.324), 0.565		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.455 (0.029, 7.146), 0.575		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.009 (-0.045, 0.027), 0.617		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.1a
Summary of All Adverse Events by Age Group
Safety Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Intracranial Bleeding AESI	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [3]
Any AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.1a
Summary of All Adverse Events by Age Group
Safety Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Intracranial Bleeding AESI	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [3]
Grade 1-2 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade 1-2 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.1a
Summary of All Adverse Events by Age Group
Safety Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Intracranial Bleeding AESI	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.1a
Summary of All Adverse Events by Age Group
Safety Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Intracranial Bleeding AESI	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.1a
Summary of All Adverse Events by Age Group
Safety Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Oedema CMQ	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [3]
Any AEs, n (%)	8 (13.3)	30 (22.7)	0	6 (66.7)	0.942
Odds Ratio (95% CIs) [1], P-Value		1.912 (0.818, 4.466), 0.130		NE (NE, NE), 0.001	
Relative Risk (95% CIs) [2], P-Value		1.705 (0.832, 3.494), 0.145		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.094 (-0.018, 0.206), 0.100		0.667 (0.359, 0.975), <0.0001	
AEs Related to Study Drug, n (%)	5 (8.3)	20 (15.2)	0	6 (66.7)	0.949
Odds Ratio (95% CIs) [1], P-Value		1.964 (0.700, 5.512), 0.193		NE (NE, NE), 0.001	
Relative Risk (95% CIs) [2], P-Value		1.818 (0.716, 4.614), 0.208		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.068 (-0.025, 0.161), 0.150		0.667 (0.359, 0.975), <0.0001	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.1a
Summary of All Adverse Events by Age Group
Safety Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Oedema CMQ	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [3]
Grade 1-2 AEs, n (%)	8 (13.3)	30 (22.7)	0	6 (66.7)	0.942
Odds Ratio (95% CIs) [1], P-Value		1.912 (0.818, 4.466), 0.130		NE (NE, NE), 0.001	
Relative Risk (95% CIs) [2], P-Value		1.705 (0.832, 3.494), 0.145		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.094 (-0.018, 0.206), 0.100		0.667 (0.359, 0.975), <0.0001	
Grade 1-2 AEs Related to Study Drug, n (%)	5 (8.3)	20 (15.2)	0	6 (66.7)	0.949
Odds Ratio (95% CIs) [1], P-Value		1.964 (0.700, 5.512), 0.193		NE (NE, NE), 0.001	
Relative Risk (95% CIs) [2], P-Value		1.818 (0.716, 4.614), 0.208		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.068 (-0.025, 0.161), 0.150		0.667 (0.359, 0.975), <0.0001	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.1a
Summary of All Adverse Events by Age Group
Safety Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Oedema CMQ	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	1 (0.8)	0	0	0.982
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.499		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.008 (-0.007, 0.022), 0.315		NA (NA, NA), NA	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	1 (0.8)	0	0	0.982
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.499		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.008 (-0.007, 0.022), 0.315		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.1a
Summary of All Adverse Events by Age Group
Safety Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Oedema CMQ	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.2a
Summary of All Adverse Events by Sex
Safety Population, Part 2 (Part 2 Baseline)

	Male		Female		
Overall	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [3]
Any AEs, n (%)	16 (94.1)	36 (87.8)	50 (92.6)	92 (92.0)	0.583
Odds Ratio (95% CIs) [1], P-Value		0.450 (0.049, 4.170), 0.472		0.920 (0.264, 3.207), 0.896	
Relative Risk (95% CIs) [2], P-Value		0.933 (0.791, 1.100), 0.409		0.994 (0.904, 1.093), 0.895	
Risk Difference (95% CIs) [2], P-Value		-0.063 (-0.213, 0.087), 0.410		-0.006 (-0.094, 0.082), 0.895	
AEs Related to Study Drug, n (%)	5 (29.4)	19 (46.3)	27 (50.0)	58 (58.0)	0.565
Odds Ratio (95% CIs) [1], P-Value		2.073 (0.618, 6.954), 0.233		1.381 (0.710, 2.685), 0.341	
Relative Risk (95% CIs) [2], P-Value		1.576 (0.703, 3.530), 0.269		1.160 (0.847, 1.589), 0.355	
Risk Difference (95% CIs) [2], P-Value		0.169 (-0.096, 0.434), 0.210		0.080 (-0.085, 0.245), 0.341	
Serious AEs, n (%)	1 (5.9)	1 (2.4)	7 (13.0)	6 (6.0)	0.965
Odds Ratio (95% CIs) [1], P-Value		0.400 (0.024, 6.790), 0.513		0.429 (0.136, 1.347), 0.138	
Relative Risk (95% CIs) [2], P-Value		0.415 (0.027, 6.254), 0.525		0.463 (0.164, 1.308), 0.146	
Risk Difference (95% CIs) [2], P-Value		-0.034 (-0.156, 0.087), 0.578		-0.070 (-0.171, 0.031), 0.176	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.2a
Summary of All Adverse Events by Sex
Safety Population, Part 2 (Part 2 Baseline)

	Male		Female		
Overall	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [3]
Grade 1-2 AEs, n (%)	15 (88.2)	36 (87.8)	50 (92.6)	91 (91.0)	0.875
Odds Ratio (95% CIs) [1], P-Value		0.960 (0.167, 5.508), 0.963		0.809 (0.237, 2.760), 0.734	
Relative Risk (95% CIs) [2], P-Value		0.995 (0.808, 1.225), 0.963		0.983 (0.892, 1.083), 0.727	
Risk Difference (95% CIs) [2], P-Value		-0.004 (-0.187, 0.179), 0.963		-0.016 (-0.106, 0.074), 0.728	
Grade 1-2 AEs Related to Study Drug, n (%)	5 (29.4)	19 (46.3)	27 (50.0)	58 (58.0)	0.565
Odds Ratio (95% CIs) [1], P-Value		2.073 (0.618, 6.954), 0.233		1.381 (0.710, 2.685), 0.341	
Relative Risk (95% CIs) [2], P-Value		1.576 (0.703, 3.530), 0.269		1.160 (0.847, 1.589), 0.355	
Risk Difference (95% CIs) [2], P-Value		0.169 (-0.096, 0.434), 0.210		0.080 (-0.085, 0.245), 0.341	
Grade >=3 AEs, n (%)	3 (17.6)	6 (14.6)	12 (22.2)	24 (24.0)	0.711
Odds Ratio (95% CIs) [1], P-Value		0.800 (0.175, 3.651), 0.773		1.105 (0.502, 2.432), 0.804	
Relative Risk (95% CIs) [2], P-Value		0.829 (0.234, 2.939), 0.772		1.080 (0.588, 1.985), 0.804	
Risk Difference (95% CIs) [2], P-Value		-0.030 (-0.241, 0.181), 0.780		0.018 (-0.121, 0.157), 0.802	
Grade >=3 AEs Related to Study Drug, n (%)	0	1 (2.4)	2 (3.7)	2 (2.0)	0.946
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.516		0.531 (0.073, 3.876), 0.526	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.540 (0.078, 3.727), 0.532	
Risk Difference (95% CIs) [2], P-Value		0.024 (-0.023, 0.072), 0.311		-0.017 (-0.074, 0.040), 0.560	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.2a
Summary of All Adverse Events by Sex
Safety Population, Part 2 (Part 2 Baseline)

	Male		Female		
Overall	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	2 (11.8)	1 (2.4)	7 (13.0)	11 (11.0)	0.275
Odds Ratio (95% CIs) [1], P-Value		0.188 (0.016, 2.223), 0.144		0.830 (0.302, 2.282), 0.718	
Relative Risk (95% CIs) [2], P-Value		0.207 (0.020, 2.137), 0.186		0.849 (0.349, 2.062), 0.717	
Risk Difference (95% CIs) [2], P-Value		-0.093 (-0.254, 0.067), 0.254		-0.020 (-0.128, 0.089), 0.723	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	1 (5.9)	0	0	2 (2.0)	0.894
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.117		NE (NE, NE), 0.296	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.059 (-0.171, 0.053), 0.303		0.020 (-0.007, 0.047), 0.153	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	1 (2.4)	1 (1.9)	2 (2.0)	0.954
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.516		1.082 (0.096, 12.208), 0.949	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.080 (0.100, 11.640), 0.949	
Risk Difference (95% CIs) [2], P-Value		0.024 (-0.023, 0.072), 0.311		0.001 (-0.044, 0.047), 0.949	
Related AEs Leading to Interruption of Study Drug, n (%)	1 (5.9)	0	3 (5.6)	5 (5.0)	0.952
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.117		0.895 (0.205, 3.896), 0.882	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.900 (0.224, 3.623), 0.882	
Risk Difference (95% CIs) [2], P-Value		-0.059 (-0.171, 0.053), 0.303		-0.006 (-0.080, 0.069), 0.884	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.2a
Summary of All Adverse Events by Sex
Safety Population, Part 2 (Part 2 Baseline)

	Male		Female		
Overall	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	1 (5.9)	0	0	1 (1.0)	0.901
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.117		NE (NE, NE), 0.461	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.059 (-0.171, 0.053), 0.303		0.010 (-0.010, 0.030), 0.315	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	1 (1.9)	2 (2.0)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.082 (0.096, 12.208), 0.949	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.080 (0.100, 11.640), 0.949	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.001 (-0.044, 0.047), 0.949	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.2a
Summary of All Adverse Events by Sex
Safety Population, Part 2 (Part 2 Baseline)

	Male		Female		
Cognitive Effects AESI	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [3]
Any AEs, n (%)	1 (5.9)	1 (2.4)	2 (3.7)	3 (3.0)	0.684
Odds Ratio (95% CIs) [1], P-Value		0.400 (0.024, 6.790), 0.513		0.804 (0.130, 4.966), 0.814	
Relative Risk (95% CIs) [2], P-Value		0.415 (0.027, 6.254), 0.525		0.810 (0.140, 4.700), 0.814	
Risk Difference (95% CIs) [2], P-Value		-0.034 (-0.156, 0.087), 0.578		-0.007 (-0.067, 0.053), 0.820	
AEs Related to Study Drug, n (%)	1 (5.9)	0	1 (1.9)	3 (3.0)	0.940
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.117		1.639 (0.166, 16.151), 0.669	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.620 (0.173, 15.200), 0.673	
Risk Difference (95% CIs) [2], P-Value		-0.059 (-0.171, 0.053), 0.303		0.011 (-0.038, 0.061), 0.647	
Serious AEs, n (%)	0	0	1 (1.9)	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.172	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.054, 0.017), 0.313	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.2a
Summary of All Adverse Events by Sex
Safety Population, Part 2 (Part 2 Baseline)

	Male		Female		
Cognitive Effects AESI	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [3]
Grade 1-2 AEs, n (%)	1 (5.9)	1 (2.4)	1 (1.9)	3 (3.0)	0.448
Odds Ratio (95% CIs) [1], P-Value		0.400 (0.024, 6.790), 0.513		1.639 (0.166, 16.151), 0.669	
Relative Risk (95% CIs) [2], P-Value		0.415 (0.027, 6.254), 0.525		1.620 (0.173, 15.200), 0.673	
Risk Difference (95% CIs) [2], P-Value		-0.034 (-0.156, 0.087), 0.578		0.011 (-0.038, 0.061), 0.647	
Grade 1-2 AEs Related to Study Drug, n (%)	1 (5.9)	0	1 (1.9)	3 (3.0)	0.940
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.117		1.639 (0.166, 16.151), 0.669	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.620 (0.173, 15.200), 0.673	
Risk Difference (95% CIs) [2], P-Value		-0.059 (-0.171, 0.053), 0.303		0.011 (-0.038, 0.061), 0.647	
Grade >=3 AEs, n (%)	0	0	1 (1.9)	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.172	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.054, 0.017), 0.313	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.2a
Summary of All Adverse Events by Sex
Safety Population, Part 2 (Part 2 Baseline)

	Male		Female		
Cognitive Effects AESI	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	2 (2.0)	0.961
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.296	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.020 (-0.007, 0.047), 0.153	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	1 (5.9)	0	0	1 (1.0)	0.901
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.117		NE (NE, NE), 0.461	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.059 (-0.171, 0.053), 0.303		0.010 (-0.010, 0.030), 0.315	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	2 (2.0)	0.961
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.296	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.020 (-0.007, 0.047), 0.153	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.2a
Summary of All Adverse Events by Sex
Safety Population, Part 2 (Part 2 Baseline)

	Male		Female		
Cognitive Effects AESI	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	1 (5.9)	0	0	1 (1.0)	0.901
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.117		NE (NE, NE), 0.461	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.059 (-0.171, 0.053), 0.303		0.010 (-0.010, 0.030), 0.315	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.2a
Summary of All Adverse Events by Sex
Safety Population, Part 2 (Part 2 Baseline)

	Male		Female		
Intracranial Bleeding AESI	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [3]
Any AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.2a
Summary of All Adverse Events by Sex
Safety Population, Part 2 (Part 2 Baseline)

	Male		Female		
Intracranial Bleeding AESI	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [3]
Grade 1-2 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade 1-2 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.2a
Summary of All Adverse Events by Sex
Safety Population, Part 2 (Part 2 Baseline)

	Male		Female		
Intracranial Bleeding AESI	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.2a
Summary of All Adverse Events by Sex
Safety Population, Part 2 (Part 2 Baseline)

	Male		Female		
Intracranial Bleeding AESI	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.2a
Summary of All Adverse Events by Sex
Safety Population, Part 2 (Part 2 Baseline)

	Male		Female		
Oedema CMQ	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [3]
Any AEs, n (%)	1 (5.9)	9 (22.0)	7 (13.0)	27 (27.0)	0.618
Odds Ratio (95% CIs) [1], P-Value		4.500 (0.523, 38.685), 0.140		2.483 (1.001, 6.160), 0.045	
Relative Risk (95% CIs) [2], P-Value		3.732 (0.512, 27.221), 0.194		2.083 (0.972, 4.465), 0.059	
Risk Difference (95% CIs) [2], P-Value		0.161 (-0.008, 0.330), 0.062		0.140 (0.015, 0.265), 0.028	
AEs Related to Study Drug, n (%)	0	8 (19.5)	5 (9.3)	18 (18.0)	0.947
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.050		2.151 (0.751, 6.160), 0.146	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.944 (0.764, 4.946), 0.163	
Risk Difference (95% CIs) [2], P-Value		0.195 (0.074, 0.316), 0.002		0.087 (-0.021, 0.195), 0.112	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.2a
Summary of All Adverse Events by Sex
Safety Population, Part 2 (Part 2 Baseline)

	Male		Female		
Oedema CMQ	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [3]
Grade 1-2 AEs, n (%)	1 (5.9)	9 (22.0)	7 (13.0)	27 (27.0)	0.618
Odds Ratio (95% CIs) [1], P-Value		4.500 (0.523, 38.685), 0.140		2.483 (1.001, 6.160), 0.045	
Relative Risk (95% CIs) [2], P-Value		3.732 (0.512, 27.221), 0.194		2.083 (0.972, 4.465), 0.059	
Risk Difference (95% CIs) [2], P-Value		0.161 (-0.008, 0.330), 0.062		0.140 (0.015, 0.265), 0.028	
Grade 1-2 AEs Related to Study Drug, n (%)	0	8 (19.5)	5 (9.3)	18 (18.0)	0.947
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.050		2.151 (0.751, 6.160), 0.146	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.944 (0.764, 4.946), 0.163	
Risk Difference (95% CIs) [2], P-Value		0.195 (0.074, 0.316), 0.002		0.087 (-0.021, 0.195), 0.112	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.2a
Summary of All Adverse Events by Sex
Safety Population, Part 2 (Part 2 Baseline)

	Male		Female		
Oedema CMQ	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	1 (1.0)	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.461	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.010, 0.030), 0.315	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	0	1 (1.0)	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.461	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.010, 0.030), 0.315	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.2a
Summary of All Adverse Events by Sex
Safety Population, Part 2 (Part 2 Baseline)

	Male		Female		
Oedema CMQ	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.3a
Summary of All Adverse Events by Region
Safety Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Overall	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [3]
Any AEs, n (%)	29 (87.9)	53 (88.3)	37 (97.4)	75 (92.6)	0.380
Odds Ratio (95% CIs) [1], P-Value		1.044 (0.282, 3.868), 0.948		0.338 (0.039, 2.910), 0.302	
Relative Risk (95% CIs) [2], P-Value		1.005 (0.859, 1.176), 0.949		0.951 (0.877, 1.031), 0.222	
Risk Difference (95% CIs) [2], P-Value		0.005 (-0.133, 0.142), 0.948		-0.048 (-0.124, 0.029), 0.221	
AEs Related to Study Drug, n (%)	14 (42.4)	30 (50.0)	18 (47.4)	47 (58.0)	0.834
Odds Ratio (95% CIs) [1], P-Value		1.357 (0.577, 3.194), 0.484		1.536 (0.708, 3.333), 0.276	
Relative Risk (95% CIs) [2], P-Value		1.179 (0.736, 1.888), 0.494		1.225 (0.835, 1.796), 0.299	
Risk Difference (95% CIs) [2], P-Value		0.076 (-0.135, 0.287), 0.481		0.107 (-0.085, 0.298), 0.276	
Serious AEs, n (%)	4 (12.1)	2 (3.3)	4 (10.5)	5 (6.2)	0.479
Odds Ratio (95% CIs) [1], P-Value		0.250 (0.043, 1.446), 0.099		0.559 (0.141, 2.213), 0.402	
Relative Risk (95% CIs) [2], P-Value		0.275 (0.053, 1.422), 0.124		0.586 (0.167, 2.061), 0.405	
Risk Difference (95% CIs) [2], P-Value		-0.088 (-0.208, 0.032), 0.152		-0.044 (-0.154, 0.067), 0.441	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.3a
Summary of All Adverse Events by Region
Safety Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Overall	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [3]
Grade 1-2 AEs, n (%)	28 (84.8)	53 (88.3)	37 (97.4)	74 (91.4)	0.216
Odds Ratio (95% CIs) [1], P-Value		1.352 (0.393, 4.652), 0.631		0.286 (0.034, 2.409), 0.222	
Relative Risk (95% CIs) [2], P-Value		1.041 (0.877, 1.235), 0.645		0.938 (0.862, 1.021), 0.142	
Risk Difference (95% CIs) [2], P-Value		0.035 (-0.112, 0.182), 0.642		-0.060 (-0.140, 0.019), 0.139	
Grade 1-2 AEs Related to Study Drug, n (%)	14 (42.4)	30 (50.0)	18 (47.4)	47 (58.0)	0.834
Odds Ratio (95% CIs) [1], P-Value		1.357 (0.577, 3.194), 0.484		1.536 (0.708, 3.333), 0.276	
Relative Risk (95% CIs) [2], P-Value		1.179 (0.736, 1.888), 0.494		1.225 (0.835, 1.796), 0.299	
Risk Difference (95% CIs) [2], P-Value		0.076 (-0.135, 0.287), 0.481		0.107 (-0.085, 0.298), 0.276	
Grade >=3 AEs, n (%)	7 (21.2)	13 (21.7)	8 (21.1)	17 (21.0)	0.965
Odds Ratio (95% CIs) [1], P-Value		1.027 (0.364, 2.896), 0.959		0.996 (0.387, 2.564), 0.994	
Relative Risk (95% CIs) [2], P-Value		1.021 (0.452, 2.307), 0.959		0.997 (0.472, 2.104), 0.994	
Risk Difference (95% CIs) [2], P-Value		0.005 (-0.170, 0.179), 0.959		-0.001 (-0.158, 0.156), 0.994	
Grade >=3 AEs Related to Study Drug, n (%)	1 (3.0)	2 (3.3)	1 (2.6)	1 (1.2)	0.646
Odds Ratio (95% CIs) [1], P-Value		1.103 (0.096, 12.647), 0.937		0.463 (0.028, 7.599), 0.580	
Relative Risk (95% CIs) [2], P-Value		1.100 (0.104, 11.680), 0.937		0.469 (0.030, 7.301), 0.589	
Risk Difference (95% CIs) [2], P-Value		0.003 (-0.071, 0.077), 0.936		-0.014 (-0.070, 0.042), 0.627	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.3a
Summary of All Adverse Events by Region
Safety Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Overall	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	5 (15.2)	5 (8.3)	4 (10.5)	7 (8.6)	0.628
Odds Ratio (95% CIs) [1], P-Value		0.509 (0.136, 1.907), 0.310		0.804 (0.220, 2.932), 0.741	
Relative Risk (95% CIs) [2], P-Value		0.550 (0.172, 1.762), 0.314		0.821 (0.256, 2.636), 0.740	
Risk Difference (95% CIs) [2], P-Value		-0.068 (-0.209, 0.073), 0.343		-0.019 (-0.134, 0.096), 0.748	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	1 (3.0)	2 (3.3)	0	0	>0.999
Odds Ratio (95% CIs) [1], P-Value		1.103 (0.096, 12.647), 0.937		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		1.100 (0.104, 11.680), 0.937		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.003 (-0.071, 0.077), 0.936		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	1 (1.7)	1 (2.6)	2 (2.5)	0.958
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.456		0.937 (0.082, 10.661), 0.958	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.938 (0.088, 10.030), 0.958	
Risk Difference (95% CIs) [2], P-Value		0.017 (-0.016, 0.049), 0.313		-0.002 (-0.063, 0.059), 0.958	
Related AEs Leading to Interruption of Study Drug, n (%)	2 (6.1)	3 (5.0)	2 (5.3)	2 (2.5)	0.675
Odds Ratio (95% CIs) [1], P-Value		0.816 (0.129, 5.146), 0.828		0.456 (0.062, 3.364), 0.430	
Relative Risk (95% CIs) [2], P-Value		0.825 (0.145, 4.691), 0.828		0.469 (0.069, 3.205), 0.440	
Risk Difference (95% CIs) [2], P-Value		-0.011 (-0.109, 0.088), 0.833		-0.028 (-0.107, 0.051), 0.486	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.3a
Summary of All Adverse Events by Region
Safety Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Overall	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	1 (3.0)	1 (1.7)	0	0	0.997
Odds Ratio (95% CIs) [1], P-Value		0.542 (0.033, 8.964), 0.664		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.550 (0.036, 8.510), 0.669		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.014 (-0.080, 0.053), 0.689		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	1 (1.7)	1 (2.6)	1 (1.2)	0.960
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.456		0.463 (0.028, 7.599), 0.580	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.469 (0.030, 7.301), 0.589	
Risk Difference (95% CIs) [2], P-Value		0.017 (-0.016, 0.049), 0.313		-0.014 (-0.070, 0.042), 0.627	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.3a
Summary of All Adverse Events by Region
Safety Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Cognitive Effects AESI	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [3]
Any AEs, n (%)	2 (6.1)	2 (3.3)	1 (2.6)	2 (2.5)	0.727
Odds Ratio (95% CIs) [1], P-Value		0.534 (0.072, 3.981), 0.535		0.937 (0.082, 10.661), 0.958	
Relative Risk (95% CIs) [2], P-Value		0.550 (0.081, 3.727), 0.540		0.938 (0.088, 10.030), 0.958	
Risk Difference (95% CIs) [2], P-Value		-0.027 (-0.120, 0.066), 0.566		-0.002 (-0.063, 0.059), 0.958	
AEs Related to Study Drug, n (%)	1 (3.0)	1 (1.7)	1 (2.6)	2 (2.5)	0.773
Odds Ratio (95% CIs) [1], P-Value		0.542 (0.033, 8.964), 0.664		0.937 (0.082, 10.661), 0.958	
Relative Risk (95% CIs) [2], P-Value		0.550 (0.036, 8.510), 0.669		0.938 (0.088, 10.030), 0.958	
Risk Difference (95% CIs) [2], P-Value		-0.014 (-0.080, 0.053), 0.689		-0.002 (-0.063, 0.059), 0.958	
Serious AEs, n (%)	1 (3.0)	0	0	0	0.969
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.175		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.030 (-0.089, 0.028), 0.310		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.3a
Summary of All Adverse Events by Region
Safety Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Cognitive Effects AESI	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [3]
Grade 1-2 AEs, n (%)	1 (3.0)	2 (3.3)	1 (2.6)	2 (2.5)	0.926
Odds Ratio (95% CIs) [1], P-Value		1.103 (0.096, 12.647), 0.937		0.937 (0.082, 10.661), 0.958	
Relative Risk (95% CIs) [2], P-Value		1.100 (0.104, 11.680), 0.937		0.938 (0.088, 10.030), 0.958	
Risk Difference (95% CIs) [2], P-Value		0.003 (-0.071, 0.077), 0.936		-0.002 (-0.063, 0.059), 0.958	
Grade 1-2 AEs Related to Study Drug, n (%)	1 (3.0)	1 (1.7)	1 (2.6)	2 (2.5)	0.773
Odds Ratio (95% CIs) [1], P-Value		0.542 (0.033, 8.964), 0.664		0.937 (0.082, 10.661), 0.958	
Relative Risk (95% CIs) [2], P-Value		0.550 (0.036, 8.510), 0.669		0.938 (0.088, 10.030), 0.958	
Risk Difference (95% CIs) [2], P-Value		-0.014 (-0.080, 0.053), 0.689		-0.002 (-0.063, 0.059), 0.958	
Grade >=3 AEs, n (%)	1 (3.0)	0	0	0	0.969
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.175		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.030 (-0.089, 0.028), 0.310		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.3a
Summary of All Adverse Events by Region
Safety Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Cognitive Effects AESI	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	1 (1.7)	0	1 (1.2)	0.999
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.456		NE (NE, NE), 0.492	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.017 (-0.016, 0.049), 0.313		0.012 (-0.012, 0.036), 0.314	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	1 (3.0)	1 (1.7)	0	0	0.997
Odds Ratio (95% CIs) [1], P-Value		0.542 (0.033, 8.964), 0.664		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.550 (0.036, 8.510), 0.669		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.014 (-0.080, 0.053), 0.689		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	1 (1.7)	0	1 (1.2)	0.999
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.456		NE (NE, NE), 0.492	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.017 (-0.016, 0.049), 0.313		0.012 (-0.012, 0.036), 0.314	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.3a
Summary of All Adverse Events by Region
Safety Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Cognitive Effects AESI	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	1 (3.0)	1 (1.7)	0	0	0.997
Odds Ratio (95% CIs) [1], P-Value		0.542 (0.033, 8.964), 0.664		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.550 (0.036, 8.510), 0.669		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.014 (-0.080, 0.053), 0.689		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.3a
Summary of All Adverse Events by Region
Safety Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Intracranial Bleeding AESI	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [3]
Any AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.3a
Summary of All Adverse Events by Region
Safety Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Intracranial Bleeding AESI	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [3]
Grade 1-2 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade 1-2 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.3a
Summary of All Adverse Events by Region
Safety Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Intracranial Bleeding AESI	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.3a
Summary of All Adverse Events by Region
Safety Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Intracranial Bleeding AESI	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.3a
Summary of All Adverse Events by Region
Safety Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Oedema CMQ	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [3]
Any AEs, n (%)	5 (15.2)	15 (25.0)	3 (7.9)	21 (25.9)	0.366
Odds Ratio (95% CIs) [1], P-Value		1.867 (0.611, 5.702), 0.269		4.083 (1.136, 14.679), 0.022	
Relative Risk (95% CIs) [2], P-Value		1.650 (0.658, 4.135), 0.285		3.284 (1.043, 10.337), 0.042	
Risk Difference (95% CIs) [2], P-Value		0.098 (-0.066, 0.263), 0.240		0.180 (0.052, 0.309), 0.006	
AEs Related to Study Drug, n (%)	3 (9.1)	9 (15.0)	2 (5.3)	17 (21.0)	0.342
Odds Ratio (95% CIs) [1], P-Value		1.765 (0.443, 7.031), 0.416		4.781 (1.045, 21.883), 0.029	
Relative Risk (95% CIs) [2], P-Value		1.650 (0.480, 5.677), 0.427		3.988 (0.970, 16.392), 0.055	
Risk Difference (95% CIs) [2], P-Value		0.059 (-0.074, 0.192), 0.385		0.157 (0.044, 0.271), 0.007	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.3a
Summary of All Adverse Events by Region
Safety Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Oedema CMQ	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [3]
Grade 1-2 AEs, n (%)	5 (15.2)	15 (25.0)	3 (7.9)	21 (25.9)	0.366
Odds Ratio (95% CIs) [1], P-Value		1.867 (0.611, 5.702), 0.269		4.083 (1.136, 14.679), 0.022	
Relative Risk (95% CIs) [2], P-Value		1.650 (0.658, 4.135), 0.285		3.284 (1.043, 10.337), 0.042	
Risk Difference (95% CIs) [2], P-Value		0.098 (-0.066, 0.263), 0.240		0.180 (0.052, 0.309), 0.006	
Grade 1-2 AEs Related to Study Drug, n (%)	3 (9.1)	9 (15.0)	2 (5.3)	17 (21.0)	0.342
Odds Ratio (95% CIs) [1], P-Value		1.765 (0.443, 7.031), 0.416		4.781 (1.045, 21.883), 0.029	
Relative Risk (95% CIs) [2], P-Value		1.650 (0.480, 5.677), 0.427		3.988 (0.970, 16.392), 0.055	
Risk Difference (95% CIs) [2], P-Value		0.059 (-0.074, 0.192), 0.385		0.157 (0.044, 0.271), 0.007	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.3a
Summary of All Adverse Events by Region
Safety Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Oedema CMQ	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	1 (1.7)	0	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.456		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.017 (-0.016, 0.049), 0.313		NA (NA, NA), NA	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	1 (1.7)	0	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.456		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.017 (-0.016, 0.049), 0.313		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.3a
Summary of All Adverse Events by Region
Safety Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Oedema CMQ	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Any AEs						
United States	24/28 (85.7)	45/52 (86.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	14/15 (93.3)	17/19 (89.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	6/6 (100.0)	9/11 (81.8)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	3/3 (100.0)	14/14 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	5/5 (100.0)	11/11 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	5/5 (100.0)	8/8 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	3/3 (100.0)	8/9 (88.9)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	3/3 (100.0)	5/5 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	1/1 (100.0)	3/3 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	3/4 (75.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	1/1 (100.0)	2/2 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	1/1 (100.0)	2/2 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	1/1 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Related to Study Drug						
United States	12/28 (42.9)	27/52 (51.9)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	10/15 (66.7)	13/19 (68.4)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	1/6 (16.7)	3/11 (27.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	8/14 (57.1)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	3/5 (60.0)	6/11 (54.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	2/5 (40.0)	3/8 (37.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	1/3 (33.3)	3/9 (33.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	1/3 (33.3)	5/5 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	1/1 (100.0)	2/3 (66.7)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	2/4 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	2/2 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	1/1 (100.0)	2/2 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	1/1 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Serious AEs						
United States	3/28 (10.7)	2/52 (3.8)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	2/15 (13.3)	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	1/3 (33.3)	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	1/5 (20.0)	2/11 (18.2)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	1/5 (20.0)	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	1/3 (33.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	1/2 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	1/2 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Serious AEs Related to Study Drug						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade 1-2 AEs						
United States	23/28 (82.1)	45/52 (86.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	14/15 (93.3)	16/19 (84.2)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	6/6 (100.0)	9/11 (81.8)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	3/3 (100.0)	14/14 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	5/5 (100.0)	11/11 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	5/5 (100.0)	8/8 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	3/3 (100.0)	8/9 (88.9)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	3/3 (100.0)	5/5 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	1/1 (100.0)	3/3 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	3/4 (75.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	1/1 (100.0)	2/2 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	1/1 (100.0)	2/2 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	1/1 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade 1-2 AEs Related to Study Drug						
United States	12/28 (42.9)	27/52 (51.9)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	10/15 (66.7)	13/19 (68.4)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	1/6 (16.7)	3/11 (27.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	8/14 (57.1)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	3/5 (60.0)	6/11 (54.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	2/5 (40.0)	3/8 (37.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	1/3 (33.3)	3/9 (33.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	1/3 (33.3)	5/5 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	1/1 (100.0)	2/3 (66.7)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	2/4 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	2/2 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	1/1 (100.0)	2/2 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	1/1 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade >=3 AEs						
United States	6/28 (21.4)	12/52 (23.1)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	3/15 (20.0)	4/19 (21.1)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	1/11 (9.1)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	1/3 (33.3)	4/14 (28.6)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	2/5 (40.0)	2/11 (18.2)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	1/5 (20.0)	1/8 (12.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	1/3 (33.3)	1/5 (20.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	1/3 (33.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	1/4 (25.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	1/2 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	1/1 (100.0)	2/2 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade >=3 AEs Related to Study Drug						
United States	1/28 (3.6)	2/52 (3.8)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	1/2 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	1/1 (100.0)	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality						
United States	4/28 (14.3)	4/52 (7.7)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	2/15 (13.3)	1/19 (5.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	1/5 (20.0)	2/11 (18.2)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	1/5 (20.0)	1/8 (12.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	1/9 (11.1)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	1/3 (33.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	1/2 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	1/1 (100.0)	1/2 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Leading to Reduction of Study Drug Regardless of Causality						
United States	1/28 (3.6)	2/52 (3.8)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality						
United States	0/28	1/52 (1.9)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	1/9 (11.1)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	1/2 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	1/1 (100.0)	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Related AEs Leading to Interruption of Study Drug						
United States	1/28 (3.6)	2/52 (3.8)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	1/15 (6.7)	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	1/5 (20.0)	1/8 (12.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	1/9 (11.1)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	1/1 (100.0)	1/2 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Related AEs Leading to Reduction of Study Drug						
United States	1/28 (3.6)	1/52 (1.9)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Related AEs Leading to Permanent Discontinuation of Study Drug						
United States	0/28	1/52 (1.9)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	1/9 (11.1)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	1/1 (100.0)	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Overall	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AE leading to Death						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Any AEs						
United States	2/28 (7.1)	2/52 (3.8)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	1/14 (7.1)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	1/5 (20.0)	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	1/2 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Related to Study Drug						
United States	1/28 (3.6)	1/52 (1.9)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	1/14 (7.1)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	1/5 (20.0)	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	1/2 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Serious AEs						
United States	1/28 (3.6)	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Serious AEs Related to Study Drug						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade 1-2 AEs						
United States	1/28 (3.6)	2/52 (3.8)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	1/14 (7.1)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	1/5 (20.0)	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	1/2 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade 1-2 AEs Related to Study Drug						
United States	1/28 (3.6)	1/52 (1.9)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	1/14 (7.1)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	1/5 (20.0)	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	1/2 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade >=3 AEs						
United States	1/28 (3.6)	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade >=3 AEs Related to Study Drug						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality						
United States	0/28	1/52 (1.9)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	1/2 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Leading to Reduction of Study Drug Regardless of Causality						
United States	1/28 (3.6)	1/52 (1.9)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Related AEs Leading to Interruption of Study Drug						
United States	0/28	1/52 (1.9)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	1/2 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Related AEs Leading to Reduction of Study Drug						
United States	1/28 (3.6)	1/52 (1.9)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Related AEs Leading to Permanent Discontinuation of Study Drug						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Cognitive Effects AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AE leading to Death						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Any AEs						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Related to Study Drug						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Serious AEs						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Serious AEs Related to Study Drug						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade 1-2 AEs						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade 1-2 AEs Related to Study Drug						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade >=3 AEs						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade >=3 AEs Related to Study Drug						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Leading to Reduction of Study Drug Regardless of Causality						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Related AEs Leading to Interruption of Study Drug						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Related AEs Leading to Reduction of Study Drug						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Related AEs Leading to Permanent Discontinuation of Study Drug						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Intracranial Bleeding AESI	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AE leading to Death						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Any AEs						
United States	4/28 (14.3)	11/52 (21.2)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	1/15 (6.7)	4/19 (21.1)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	2/11 (18.2)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	7/14 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	2/11 (18.2)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	1/5 (20.0)	4/8 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	1/9 (11.1)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	2/5 (40.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	1/3 (33.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	1/4 (25.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	1/1 (100.0)	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	1/1 (100.0)	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	1/1 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Related to Study Drug						
United States	3/28 (10.7)	8/52 (15.4)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	1/15 (6.7)	3/19 (15.8)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	2/11 (18.2)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	7/14 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	2/11 (18.2)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	1/8 (12.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	2/5 (40.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	1/1 (100.0)	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	1/1 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Serious AEs						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Serious AEs Related to Study Drug						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade 1-2 AEs						
United States	4/28 (14.3)	11/52 (21.2)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	1/15 (6.7)	4/19 (21.1)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	2/11 (18.2)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	7/14 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	2/11 (18.2)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	1/5 (20.0)	4/8 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	1/9 (11.1)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	2/5 (40.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	1/3 (33.3)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	1/4 (25.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	1/1 (100.0)	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	1/1 (100.0)	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	1/1 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade 1-2 AEs Related to Study Drug						
United States	3/28 (10.7)	8/52 (15.4)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	1/15 (6.7)	3/19 (15.8)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	2/11 (18.2)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	7/14 (50.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	2/11 (18.2)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	1/8 (12.5)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	2/5 (40.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	1/1 (100.0)	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	1/1 (100.0)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade >=3 AEs						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Grade >=3 AEs Related to Study Drug						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality						
United States	0/28	1/52 (1.9)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Leading to Reduction of Study Drug Regardless of Causality						
United States	0/28	1/52 (1.9)	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Related AEs Leading to Interruption of Study Drug						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Related AEs Leading to Reduction of Study Drug						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
Related AEs Leading to Permanent Discontinuation of Study Drug						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.9a
Summary of All Adverse Events by Country
Safety Population, Part 2 (Part 2 Baseline)

Oedema CMQ	Placebo (N=71) n/N n (%)	Ava 25 mg (N=141) n/N n (%)	Odds Ratio (95% CIs) [1] P-Value	Relative Risk (95% CIs) [2] P-Value	Risk Difference (95% CIs) [2] P-Value	P-Value [3]
AE leading to Death						
United States	0/28	0/52	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Germany	0/15	0/19	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
France	0/6	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Spain	0/3	0/14	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
United Kingdom	0/5	0/11	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Canada	0/5	0/8	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Netherlands	0/3	0/9	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Norway	0/3	0/5	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Belgium	0/1	0/3	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Italy	0/0	0/4	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Sweden	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Switzerland	0/1	0/2	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-
Denmark	0/0	0/1	NA (NA, NA) NA	NA (NA, NA) NA	NA (NA, NA) NA	-

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-country-a.sas Date: 11:50/20JUL2023

Table 35.3.1.1.1.4a
Summary of All Adverse Events by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Overall	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [3]
Any AEs, n (%)	25 (96.2)	46 (88.5)	41 (91.1)	81 (93.1)	0.261
Odds Ratio (95% CIs) [1], P-Value		0.307 (0.035, 2.692), 0.262		1.317 (0.352, 4.929), 0.682	
Relative Risk (95% CIs) [2], P-Value		0.920 (0.812, 1.042), 0.190		1.022 (0.918, 1.138), 0.694	
Risk Difference (95% CIs) [2], P-Value		-0.077 (-0.191, 0.037), 0.186		0.020 (-0.079, 0.119), 0.692	
AEs Related to Study Drug, n (%)	12 (46.2)	23 (44.2)	20 (44.4)	53 (60.9)	0.221
Odds Ratio (95% CIs) [1], P-Value		0.925 (0.359, 2.382), 0.872		1.949 (0.940, 4.039), 0.071	
Relative Risk (95% CIs) [2], P-Value		0.958 (0.572, 1.604), 0.871		1.371 (0.949, 1.979), 0.093	
Risk Difference (95% CIs) [2], P-Value		-0.019 (-0.254, 0.215), 0.872		0.165 (-0.013, 0.342), 0.069	
Serious AEs, n (%)	3 (11.5)	1 (1.9)	5 (11.1)	6 (6.9)	0.307
Odds Ratio (95% CIs) [1], P-Value		0.150 (0.015, 1.524), 0.070		0.593 (0.170, 2.060), 0.406	
Relative Risk (95% CIs) [2], P-Value		0.167 (0.018, 1.525), 0.113		0.621 (0.200, 1.923), 0.409	
Risk Difference (95% CIs) [2], P-Value		-0.096 (-0.225, 0.032), 0.142		-0.042 (-0.148, 0.064), 0.436	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.4a
Summary of All Adverse Events by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Overall	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [3]
Grade 1-2 AEs, n (%)	25 (96.2)	45 (86.5)	40 (88.9)	81 (93.1)	0.138
Odds Ratio (95% CIs) [1], P-Value		0.257 (0.030, 2.211), 0.187		1.688 (0.486, 5.865), 0.406	
Relative Risk (95% CIs) [2], P-Value		0.900 (0.789, 1.027), 0.117		1.047 (0.931, 1.179), 0.442	
Risk Difference (95% CIs) [2], P-Value		-0.096 (-0.215, 0.022), 0.112		0.042 (-0.064, 0.148), 0.436	
Grade 1-2 AEs Related to Study Drug, n (%)	12 (46.2)	23 (44.2)	20 (44.4)	53 (60.9)	0.221
Odds Ratio (95% CIs) [1], P-Value		0.925 (0.359, 2.382), 0.872		1.949 (0.940, 4.039), 0.071	
Relative Risk (95% CIs) [2], P-Value		0.958 (0.572, 1.604), 0.871		1.371 (0.949, 1.979), 0.093	
Risk Difference (95% CIs) [2], P-Value		-0.019 (-0.254, 0.215), 0.872		0.165 (-0.013, 0.342), 0.069	
Grade >=3 AEs, n (%)	6 (23.1)	11 (21.2)	9 (20.0)	19 (21.8)	0.761
Odds Ratio (95% CIs) [1], P-Value		0.894 (0.289, 2.766), 0.846		1.118 (0.459, 2.722), 0.806	
Relative Risk (95% CIs) [2], P-Value		0.917 (0.382, 2.202), 0.846		1.092 (0.539, 2.214), 0.807	
Risk Difference (95% CIs) [2], P-Value		-0.019 (-0.216, 0.177), 0.848		0.018 (-0.127, 0.164), 0.804	
Grade >=3 AEs Related to Study Drug, n (%)	1 (3.8)	2 (3.8)	1 (2.2)	1 (1.1)	0.724
Odds Ratio (95% CIs) [1], P-Value		1.000 (0.086, 11.565), >0.999		0.512 (0.031, 8.376), 0.632	
Relative Risk (95% CIs) [2], P-Value		1.000 (0.095, 10.526), >0.999		0.517 (0.033, 8.078), 0.638	
Risk Difference (95% CIs) [2], P-Value		0.000 (-0.091, 0.091), >0.999		-0.011 (-0.059, 0.038), 0.665	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.4a
Summary of All Adverse Events by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Overall	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	5 (19.2)	2 (3.8)	4 (8.9)	10 (11.5)	0.054
Odds Ratio (95% CIs) [1], P-Value		0.168 (0.030, 0.936), 0.025		1.331 (0.393, 4.508), 0.645	
Relative Risk (95% CIs) [2], P-Value		0.200 (0.042, 0.962), 0.045		1.293 (0.429, 3.894), 0.648	
Risk Difference (95% CIs) [2], P-Value		-0.154 (-0.314, 0.006), 0.060		0.026 (-0.081, 0.133), 0.633	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	1 (3.8)	1 (1.9)	0	1 (1.1)	0.955
Odds Ratio (95% CIs) [1], P-Value		0.490 (0.029, 8.165), 0.612		NE (NE, NE), 0.470	
Relative Risk (95% CIs) [2], P-Value		0.500 (0.033, 7.678), 0.619		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.019 (-0.102, 0.064), 0.649		0.011 (-0.011, 0.034), 0.315	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	1 (3.8)	2 (3.8)	0	1 (1.1)	0.953
Odds Ratio (95% CIs) [1], P-Value		1.000 (0.086, 11.565), >0.999		NE (NE, NE), 0.470	
Relative Risk (95% CIs) [2], P-Value		1.000 (0.095, 10.526), >0.999		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.000 (-0.091, 0.091), >0.999		0.011 (-0.011, 0.034), 0.315	
Related AEs Leading to Interruption of Study Drug, n (%)	4 (15.4)	1 (1.9)	0	4 (4.6)	0.940
Odds Ratio (95% CIs) [1], P-Value		0.108 (0.011, 1.021), 0.022		NE (NE, NE), 0.144	
Relative Risk (95% CIs) [2], P-Value		0.125 (0.015, 1.063), 0.057		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.135 (-0.278, 0.009), 0.066		0.046 (0.002, 0.090), 0.041	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.4a
Summary of All Adverse Events by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Overall	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	1 (3.8)	1 (1.9)	0	0	0.998
Odds Ratio (95% CIs) [1], P-Value		0.490 (0.029, 8.165), 0.612		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.500 (0.033, 7.678), 0.619		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.019 (-0.102, 0.064), 0.649		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	1 (3.8)	1 (1.9)	0	1 (1.1)	0.955
Odds Ratio (95% CIs) [1], P-Value		0.490 (0.029, 8.165), 0.612		NE (NE, NE), 0.470	
Relative Risk (95% CIs) [2], P-Value		0.500 (0.033, 7.678), 0.619		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.019 (-0.102, 0.064), 0.649		0.011 (-0.011, 0.034), 0.315	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.4a
Summary of All Adverse Events by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Cognitive Effects AESI	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [3]
Any AEs, n (%)	2 (7.7)	1 (1.9)	1 (2.2)	3 (3.4)	0.267
Odds Ratio (95% CIs) [1], P-Value		0.235 (0.020, 2.724), 0.212		1.571 (0.159, 15.555), 0.697	
Relative Risk (95% CIs) [2], P-Value		0.250 (0.024, 2.631), 0.248		1.552 (0.166, 14.494), 0.700	
Risk Difference (95% CIs) [2], P-Value		-0.058 (-0.167, 0.051), 0.300		0.012 (-0.045, 0.070), 0.677	
AEs Related to Study Drug, n (%)	1 (3.8)	1 (1.9)	1 (2.2)	2 (2.3)	0.693
Odds Ratio (95% CIs) [1], P-Value		0.490 (0.029, 8.165), 0.612		1.035 (0.091, 11.735), 0.978	
Relative Risk (95% CIs) [2], P-Value		0.500 (0.033, 7.678), 0.619		1.034 (0.096, 11.103), 0.978	
Risk Difference (95% CIs) [2], P-Value		-0.019 (-0.102, 0.064), 0.649		0.001 (-0.053, 0.054), 0.978	
Serious AEs, n (%)	1 (3.8)	0	0	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.155		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.112, 0.035), 0.308		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.4a
Summary of All Adverse Events by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Cognitive Effects AESI	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [3]
Grade 1-2 AEs, n (%)	1 (3.8)	1 (1.9)	1 (2.2)	3 (3.4)	0.529
Odds Ratio (95% CIs) [1], P-Value		0.490 (0.029, 8.165), 0.612		1.571 (0.159, 15.555), 0.697	
Relative Risk (95% CIs) [2], P-Value		0.500 (0.033, 7.678), 0.619		1.552 (0.166, 14.494), 0.700	
Risk Difference (95% CIs) [2], P-Value		-0.019 (-0.102, 0.064), 0.649		0.012 (-0.045, 0.070), 0.677	
Grade 1-2 AEs Related to Study Drug, n (%)	1 (3.8)	1 (1.9)	1 (2.2)	2 (2.3)	0.693
Odds Ratio (95% CIs) [1], P-Value		0.490 (0.029, 8.165), 0.612		1.035 (0.091, 11.735), 0.978	
Relative Risk (95% CIs) [2], P-Value		0.500 (0.033, 7.678), 0.619		1.034 (0.096, 11.103), 0.978	
Risk Difference (95% CIs) [2], P-Value		-0.019 (-0.102, 0.064), 0.649		0.001 (-0.053, 0.054), 0.978	
Grade >=3 AEs, n (%)	1 (3.8)	0	0	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.155		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.112, 0.035), 0.308		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.4a
Summary of All Adverse Events by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Cognitive Effects AESI	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	1 (1.9)	0	1 (1.1)	0.998
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.477		NE (NE, NE), 0.470	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.019 (-0.018, 0.057), 0.313		0.011 (-0.011, 0.034), 0.315	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	1 (3.8)	1 (1.9)	0	0	0.998
Odds Ratio (95% CIs) [1], P-Value		0.490 (0.029, 8.165), 0.612		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.500 (0.033, 7.678), 0.619		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.019 (-0.102, 0.064), 0.649		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	1 (1.9)	0	1 (1.1)	0.998
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.477		NE (NE, NE), 0.470	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.019 (-0.018, 0.057), 0.313		0.011 (-0.011, 0.034), 0.315	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.4a
Summary of All Adverse Events by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Cognitive Effects AESI	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	1 (3.8)	1 (1.9)	0	0	0.998
Odds Ratio (95% CIs) [1], P-Value		0.490 (0.029, 8.165), 0.612		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.500 (0.033, 7.678), 0.619		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.019 (-0.102, 0.064), 0.649		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.4a
Summary of All Adverse Events by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Intracranial Bleeding AESI	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [3]
Any AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.4a
Summary of All Adverse Events by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Intracranial Bleeding AESI	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [3]
Grade 1-2 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade 1-2 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.4a
Summary of All Adverse Events by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Intracranial Bleeding AESI	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.4a
Summary of All Adverse Events by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Intracranial Bleeding AESI	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.4a
Summary of All Adverse Events by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Oedema CMQ	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [3]
Any AEs, n (%)	2 (7.7)	10 (19.2)	6 (13.3)	26 (29.9)	0.974
Odds Ratio (95% CIs) [1], P-Value		2.857 (0.577, 14.136), 0.183		2.770 (1.046, 7.341), 0.035	
Relative Risk (95% CIs) [2], P-Value		2.500 (0.590, 10.587), 0.213		2.241 (0.996, 5.046), 0.051	
Risk Difference (95% CIs) [2], P-Value		0.115 (-0.033, 0.264), 0.127		0.166 (0.027, 0.304), 0.019	
AEs Related to Study Drug, n (%)	1 (3.8)	9 (17.3)	4 (8.9)	17 (19.5)	0.547
Odds Ratio (95% CIs) [1], P-Value		5.233 (0.626, 43.767), 0.094		2.489 (0.784, 7.904), 0.113	
Relative Risk (95% CIs) [2], P-Value		4.500 (0.602, 33.640), 0.143		2.198 (0.786, 6.145), 0.133	
Risk Difference (95% CIs) [2], P-Value		0.135 (0.008, 0.261), 0.037		0.107 (-0.011, 0.224), 0.076	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.4a
Summary of All Adverse Events by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Oedema CMQ	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [3]
Grade 1-2 AEs, n (%)	2 (7.7)	10 (19.2)	6 (13.3)	26 (29.9)	0.974
Odds Ratio (95% CIs) [1], P-Value		2.857 (0.577, 14.136), 0.183		2.770 (1.046, 7.341), 0.035	
Relative Risk (95% CIs) [2], P-Value		2.500 (0.590, 10.587), 0.213		2.241 (0.996, 5.046), 0.051	
Risk Difference (95% CIs) [2], P-Value		0.115 (-0.033, 0.264), 0.127		0.166 (0.027, 0.304), 0.019	
Grade 1-2 AEs Related to Study Drug, n (%)	1 (3.8)	9 (17.3)	4 (8.9)	17 (19.5)	0.547
Odds Ratio (95% CIs) [1], P-Value		5.233 (0.626, 43.767), 0.094		2.489 (0.784, 7.904), 0.113	
Relative Risk (95% CIs) [2], P-Value		4.500 (0.602, 33.640), 0.143		2.198 (0.786, 6.145), 0.133	
Risk Difference (95% CIs) [2], P-Value		0.135 (0.008, 0.261), 0.037		0.107 (-0.011, 0.224), 0.076	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.4a
Summary of All Adverse Events by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Oedema CMQ	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	1 (1.1)	0.968
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.470	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.011 (-0.011, 0.034), 0.315	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	0	1 (1.1)	0.968
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.470	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.011 (-0.011, 0.034), 0.315	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.4a
Summary of All Adverse Events by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Oedema CMQ	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Overall	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [3]
Any AEs, n (%)	14 (93.3)	26 (92.9)	52 (92.9)	102 (90.3)	0.851
Odds Ratio (95% CIs) [1], P-Value		0.929 (0.077, 11.164), 0.953		0.713 (0.217, 2.350), 0.577	
Relative Risk (95% CIs) [2], P-Value		0.995 (0.839, 1.179), 0.953		0.972 (0.884, 1.069), 0.557	
Risk Difference (95% CIs) [2], P-Value		-0.005 (-0.163, 0.153), 0.953		-0.026 (-0.113, 0.061), 0.558	
AEs Related to Study Drug, n (%)	7 (46.7)	9 (32.1)	25 (44.6)	68 (60.2)	0.091
Odds Ratio (95% CIs) [1], P-Value		0.541 (0.149, 1.962), 0.348		1.874 (0.981, 3.581), 0.056	
Relative Risk (95% CIs) [2], P-Value		0.689 (0.321, 1.477), 0.338		1.348 (0.971, 1.871), 0.074	
Risk Difference (95% CIs) [2], P-Value		-0.145 (-0.451, 0.161), 0.352		0.155 (-0.003, 0.314), 0.055	
Serious AEs, n (%)	1 (6.7)	3 (10.7)	7 (12.5)	4 (3.5)	0.169
Odds Ratio (95% CIs) [1], P-Value		1.680 (0.159, 17.719), 0.663		0.257 (0.072, 0.918), 0.026	
Relative Risk (95% CIs) [2], P-Value		1.607 (0.183, 14.140), 0.669		0.283 (0.086, 0.927), 0.037	
Risk Difference (95% CIs) [2], P-Value		0.040 (-0.130, 0.211), 0.642		-0.090 (-0.183, 0.003), 0.059	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Overall	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [3]
Grade 1-2 AEs, n (%)	14 (93.3)	26 (92.9)	51 (91.1)	101 (89.4)	0.932
Odds Ratio (95% CIs) [1], P-Value		0.929 (0.077, 11.164), 0.953		0.825 (0.276, 2.470), 0.731	
Relative Risk (95% CIs) [2], P-Value		0.995 (0.839, 1.179), 0.953		0.981 (0.885, 1.089), 0.723	
Risk Difference (95% CIs) [2], P-Value		-0.005 (-0.163, 0.153), 0.953		-0.017 (-0.111, 0.077), 0.724	
Grade 1-2 AEs Related to Study Drug, n (%)	7 (46.7)	9 (32.1)	25 (44.6)	68 (60.2)	0.091
Odds Ratio (95% CIs) [1], P-Value		0.541 (0.149, 1.962), 0.348		1.874 (0.981, 3.581), 0.056	
Relative Risk (95% CIs) [2], P-Value		0.689 (0.321, 1.477), 0.338		1.348 (0.971, 1.871), 0.074	
Risk Difference (95% CIs) [2], P-Value		-0.145 (-0.451, 0.161), 0.352		0.155 (-0.003, 0.314), 0.055	
Grade >=3 AEs, n (%)	1 (6.7)	12 (42.9)	14 (25.0)	18 (15.9)	0.013
Odds Ratio (95% CIs) [1], P-Value		10.500 (1.208, 91.268), 0.014		0.568 (0.259, 1.249), 0.157	
Relative Risk (95% CIs) [2], P-Value		6.429 (0.923, 44.789), 0.060		0.637 (0.343, 1.185), 0.155	
Risk Difference (95% CIs) [2], P-Value		0.362 (0.139, 0.584), 0.001		-0.091 (-0.223, 0.041), 0.178	
Grade >=3 AEs Related to Study Drug, n (%)	1 (6.7)	0	1 (1.8)	3 (2.7)	0.967
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.167		1.500 (0.152, 14.756), 0.726	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.487 (0.158, 13.971), 0.729	
Risk Difference (95% CIs) [2], P-Value		-0.067 (-0.193, 0.060), 0.301		0.009 (-0.037, 0.054), 0.709	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Overall	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	1 (6.7)	2 (7.1)	8 (14.3)	10 (8.8)	0.653
Odds Ratio (95% CIs) [1], P-Value		1.077 (0.090, 12.948), 0.953		0.583 (0.216, 1.569), 0.281	
Relative Risk (95% CIs) [2], P-Value		1.071 (0.106, 10.871), 0.953		0.619 (0.259, 1.483), 0.282	
Risk Difference (95% CIs) [2], P-Value		0.005 (-0.153, 0.163), 0.953		-0.054 (-0.160, 0.051), 0.313	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	1 (6.7)	0	0	2 (1.8)	0.929
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.167		NE (NE, NE), 0.317	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.067 (-0.193, 0.060), 0.301		0.018 (-0.007, 0.042), 0.154	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	1 (1.8)	3 (2.7)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.500 (0.152, 14.756), 0.726	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.487 (0.158, 13.971), 0.729	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.009 (-0.037, 0.054), 0.709	
Related AEs Leading to Interruption of Study Drug, n (%)	1 (6.7)	0	3 (5.4)	5 (4.4)	0.960
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.167		0.818 (0.188, 3.552), 0.788	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.826 (0.205, 3.333), 0.788	
Risk Difference (95% CIs) [2], P-Value		-0.067 (-0.193, 0.060), 0.301		-0.009 (-0.079, 0.061), 0.794	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Overall	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	1 (6.7)	0	0	1 (0.9)	0.930
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.167		NE (NE, NE), 0.480	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.067 (-0.193, 0.060), 0.301		0.009 (-0.008, 0.026), 0.315	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	1 (1.8)	2 (1.8)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.991 (0.088, 11.168), 0.994	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.991 (0.092, 10.698), 0.994	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.000 (-0.043, 0.042), 0.994	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Cognitive Effects AESI	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [3]
Any AEs, n (%)	1 (6.7)	0	2 (3.6)	4 (3.5)	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.167		0.991 (0.176, 5.580), 0.992	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.991 (0.187, 5.249), 0.992	
Risk Difference (95% CIs) [2], P-Value		-0.067 (-0.193, 0.060), 0.301		-0.000 (-0.060, 0.059), 0.992	
AEs Related to Study Drug, n (%)	1 (6.7)	0	1 (1.8)	3 (2.7)	0.967
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.167		1.500 (0.152, 14.756), 0.726	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.487 (0.158, 13.971), 0.729	
Risk Difference (95% CIs) [2], P-Value		-0.067 (-0.193, 0.060), 0.301		0.009 (-0.037, 0.054), 0.709	
Serious AEs, n (%)	0	0	1 (1.8)	0	0.971
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.154	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.018 (-0.053, 0.017), 0.313	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Cognitive Effects AESI	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [3]
Grade 1-2 AEs, n (%)	1 (6.7)	0	1 (1.8)	4 (3.5)	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.167		2.018 (0.220, 18.494), 0.526	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.982 (0.227, 17.323), 0.536	
Risk Difference (95% CIs) [2], P-Value		-0.067 (-0.193, 0.060), 0.301		0.018 (-0.031, 0.066), 0.479	
Grade 1-2 AEs Related to Study Drug, n (%)	1 (6.7)	0	1 (1.8)	3 (2.7)	0.967
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.167		1.500 (0.152, 14.756), 0.726	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.487 (0.158, 13.971), 0.729	
Risk Difference (95% CIs) [2], P-Value		-0.067 (-0.193, 0.060), 0.301		0.009 (-0.037, 0.054), 0.709	
Grade >=3 AEs, n (%)	0	0	1 (1.8)	0	0.971
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.154	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.018 (-0.053, 0.017), 0.313	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Cognitive Effects AESI	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	2 (1.8)	0.976
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.317	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.018 (-0.007, 0.042), 0.154	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	1 (6.7)	0	0	1 (0.9)	0.930
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.167		NE (NE, NE), 0.480	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.067 (-0.193, 0.060), 0.301		0.009 (-0.008, 0.026), 0.315	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	2 (1.8)	0.976
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.317	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.018 (-0.007, 0.042), 0.154	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Cognitive Effects AESI	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	1 (6.7)	0	0	1 (0.9)	0.930
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.167		NE (NE, NE), 0.480	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.067 (-0.193, 0.060), 0.301		0.009 (-0.008, 0.026), 0.315	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Intracranial Bleeding AESI	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [3]
Any AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Intracranial Bleeding AESI	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [3]
Grade 1-2 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade 1-2 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Intracranial Bleeding AESI	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Intracranial Bleeding AESI	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Oedema CMQ	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [3]
Any AEs, n (%)	2 (13.3)	6 (21.4)	6 (10.7)	30 (26.5)	0.600
Odds Ratio (95% CIs) [1], P-Value		1.773 (0.311, 10.110), 0.516		3.012 (1.172, 7.743), 0.018	
Relative Risk (95% CIs) [2], P-Value		1.607 (0.369, 7.006), 0.528		2.478 (1.096, 5.603), 0.029	
Risk Difference (95% CIs) [2], P-Value		0.081 (-0.149, 0.311), 0.489		0.158 (0.043, 0.273), 0.007	
AEs Related to Study Drug, n (%)	1 (6.7)	2 (7.1)	4 (7.1)	24 (21.2)	0.396
Odds Ratio (95% CIs) [1], P-Value		1.077 (0.090, 12.948), 0.953		3.506 (1.153, 10.663), 0.020	
Relative Risk (95% CIs) [2], P-Value		1.071 (0.106, 10.871), 0.953		2.973 (1.084, 8.155), 0.034	
Risk Difference (95% CIs) [2], P-Value		0.005 (-0.153, 0.163), 0.953		0.141 (0.040, 0.242), 0.006	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Oedema CMQ	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [3]
Grade 1-2 AEs, n (%)	2 (13.3)	6 (21.4)	6 (10.7)	30 (26.5)	0.600
Odds Ratio (95% CIs) [1], P-Value		1.773 (0.311, 10.110), 0.516		3.012 (1.172, 7.743), 0.018	
Relative Risk (95% CIs) [2], P-Value		1.607 (0.369, 7.006), 0.528		2.478 (1.096, 5.603), 0.029	
Risk Difference (95% CIs) [2], P-Value		0.081 (-0.149, 0.311), 0.489		0.158 (0.043, 0.273), 0.007	
Grade 1-2 AEs Related to Study Drug, n (%)	1 (6.7)	2 (7.1)	4 (7.1)	24 (21.2)	0.396
Odds Ratio (95% CIs) [1], P-Value		1.077 (0.090, 12.948), 0.953		3.506 (1.153, 10.663), 0.020	
Relative Risk (95% CIs) [2], P-Value		1.071 (0.106, 10.871), 0.953		2.973 (1.084, 8.155), 0.034	
Risk Difference (95% CIs) [2], P-Value		0.005 (-0.153, 0.163), 0.953		0.141 (0.040, 0.242), 0.006	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Oedema CMQ	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	1 (0.9)	0.975
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.480	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.009 (-0.008, 0.026), 0.315	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	0	1 (0.9)	0.975
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.480	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.009 (-0.008, 0.026), 0.315	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.5a
Summary of All Adverse Events by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Oedema CMQ	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.6a
Summary of All Adverse Events by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Overall	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [3]
Any AEs, n (%)	32 (91.4)	62 (86.1)	34 (94.4)	66 (95.7)	0.492
Odds Ratio (95% CIs) [1], P-Value		0.581 (0.149, 2.262), 0.430		1.294 (0.206, 8.119), 0.783	
Relative Risk (95% CIs) [2], P-Value		0.942 (0.821, 1.081), 0.393		1.013 (0.922, 1.112), 0.791	
Risk Difference (95% CIs) [2], P-Value		-0.053 (-0.176, 0.069), 0.395		0.012 (-0.077, 0.101), 0.790	
AEs Related to Study Drug, n (%)	17 (48.6)	44 (61.1)	15 (41.7)	33 (47.8)	0.659
Odds Ratio (95% CIs) [1], P-Value		1.664 (0.737, 3.758), 0.219		1.283 (0.569, 2.896), 0.548	
Relative Risk (95% CIs) [2], P-Value		1.258 (0.854, 1.854), 0.245		1.148 (0.726, 1.815), 0.556	
Risk Difference (95% CIs) [2], P-Value		0.125 (-0.075, 0.326), 0.220		0.062 (-0.138, 0.261), 0.545	
Serious AEs, n (%)	2 (5.7)	2 (2.8)	6 (16.7)	5 (7.2)	0.876
Odds Ratio (95% CIs) [1], P-Value		0.471 (0.064, 3.495), 0.453		0.391 (0.110, 1.382), 0.135	
Relative Risk (95% CIs) [2], P-Value		0.486 (0.071, 3.309), 0.461		0.435 (0.142, 1.328), 0.144	
Risk Difference (95% CIs) [2], P-Value		-0.029 (-0.115, 0.056), 0.502		-0.094 (-0.230, 0.042), 0.175	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.6a
Summary of All Adverse Events by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Overall	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [3]
Grade 1-2 AEs, n (%)	32 (91.4)	62 (86.1)	33 (91.7)	65 (94.2)	0.376
Odds Ratio (95% CIs) [1], P-Value		0.581 (0.149, 2.262), 0.430		1.477 (0.312, 6.991), 0.621	
Relative Risk (95% CIs) [2], P-Value		0.942 (0.821, 1.081), 0.393		1.028 (0.916, 1.152), 0.641	
Risk Difference (95% CIs) [2], P-Value		-0.053 (-0.176, 0.069), 0.395		0.025 (-0.080, 0.131), 0.638	
Grade 1-2 AEs Related to Study Drug, n (%)	17 (48.6)	44 (61.1)	15 (41.7)	33 (47.8)	0.659
Odds Ratio (95% CIs) [1], P-Value		1.664 (0.737, 3.758), 0.219		1.283 (0.569, 2.896), 0.548	
Relative Risk (95% CIs) [2], P-Value		1.258 (0.854, 1.854), 0.245		1.148 (0.726, 1.815), 0.556	
Risk Difference (95% CIs) [2], P-Value		0.125 (-0.075, 0.326), 0.220		0.062 (-0.138, 0.261), 0.545	
Grade >=3 AEs, n (%)	6 (17.1)	12 (16.7)	9 (25.0)	18 (26.1)	0.900
Odds Ratio (95% CIs) [1], P-Value		0.967 (0.330, 2.834), 0.951		1.059 (0.419, 2.673), 0.904	
Relative Risk (95% CIs) [2], P-Value		0.972 (0.398, 2.374), 0.951		1.043 (0.523, 2.083), 0.904	
Risk Difference (95% CIs) [2], P-Value		-0.005 (-0.156, 0.147), 0.951		0.011 (-0.164, 0.186), 0.903	
Grade >=3 AEs Related to Study Drug, n (%)	1 (2.9)	2 (2.8)	1 (2.8)	1 (1.4)	0.737
Odds Ratio (95% CIs) [1], P-Value		0.971 (0.085, 11.092), 0.981		0.515 (0.031, 8.478), 0.636	
Relative Risk (95% CIs) [2], P-Value		0.972 (0.091, 10.361), 0.981		0.522 (0.034, 8.099), 0.642	
Risk Difference (95% CIs) [2], P-Value		-0.001 (-0.068, 0.066), 0.981		-0.013 (-0.074, 0.047), 0.668	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.6a
Summary of All Adverse Events by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Overall	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	3 (8.6)	5 (6.9)	6 (16.7)	7 (10.1)	0.723
Odds Ratio (95% CIs) [1], P-Value		0.796 (0.179, 3.539), 0.764		0.565 (0.174, 1.827), 0.336	
Relative Risk (95% CIs) [2], P-Value		0.810 (0.205, 3.199), 0.764		0.609 (0.221, 1.677), 0.337	
Risk Difference (95% CIs) [2], P-Value		-0.016 (-0.126, 0.093), 0.771		-0.065 (-0.206, 0.076), 0.365	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	1 (2.8)	2 (2.9)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.045 (0.092, 11.927), 0.972	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.043 (0.098, 11.122), 0.972	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.001 (-0.065, 0.068), 0.972	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	2 (2.8)	1 (2.8)	1 (1.4)	0.952
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.320		0.515 (0.031, 8.478), 0.636	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.522 (0.034, 8.099), 0.642	
Risk Difference (95% CIs) [2], P-Value		0.028 (-0.010, 0.066), 0.151		-0.013 (-0.074, 0.047), 0.668	
Related AEs Leading to Interruption of Study Drug, n (%)	1 (2.9)	2 (2.8)	3 (8.3)	3 (4.3)	0.658
Odds Ratio (95% CIs) [1], P-Value		0.971 (0.085, 11.092), 0.981		0.500 (0.096, 2.614), 0.404	
Relative Risk (95% CIs) [2], P-Value		0.972 (0.091, 10.361), 0.981		0.522 (0.111, 2.455), 0.410	
Risk Difference (95% CIs) [2], P-Value		-0.001 (-0.068, 0.066), 0.981		-0.040 (-0.142, 0.062), 0.445	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.6a
Summary of All Adverse Events by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Overall	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	1 (2.8)	1 (1.4)	0.997
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.515 (0.031, 8.478), 0.636	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.522 (0.034, 8.099), 0.642	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.013 (-0.074, 0.047), 0.668	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	1 (1.4)	1 (2.8)	1 (1.4)	0.960
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.484		0.515 (0.031, 8.478), 0.636	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.522 (0.034, 8.099), 0.642	
Risk Difference (95% CIs) [2], P-Value		0.014 (-0.013, 0.041), 0.314		-0.013 (-0.074, 0.047), 0.668	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.6a
Summary of All Adverse Events by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Cognitive Effects AESI	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [3]
Any AEs, n (%)	0	0	3 (8.3)	4 (5.8)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.677 (0.143, 3.204), 0.621	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.696 (0.165, 2.941), 0.622	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.025 (-0.131, 0.080), 0.638	
AEs Related to Study Drug, n (%)	0	0	2 (5.6)	3 (4.3)	0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.773 (0.123, 4.848), 0.783	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.783 (0.137, 4.473), 0.783	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.012 (-0.101, 0.077), 0.790	
Serious AEs, n (%)	0	0	1 (2.8)	0	0.956
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.164	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.028 (-0.081, 0.026), 0.310	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.6a
Summary of All Adverse Events by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Cognitive Effects AESI	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [3]
Grade 1-2 AEs, n (%)	0	0	2 (5.6)	4 (5.8)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.046 (0.182, 6.004), 0.960	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.043 (0.201, 5.427), 0.960	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.002 (-0.091, 0.095), 0.959	
Grade 1-2 AEs Related to Study Drug, n (%)	0	0	2 (5.6)	3 (4.3)	0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.773 (0.123, 4.848), 0.783	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.783 (0.137, 4.473), 0.783	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.012 (-0.101, 0.077), 0.790	
Grade >=3 AEs, n (%)	0	0	1 (2.8)	0	0.956
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.164	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.028 (-0.081, 0.026), 0.310	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.6a
Summary of All Adverse Events by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Cognitive Effects AESI	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	2 (2.9)	0.951
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.302	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.029 (-0.011, 0.069), 0.151	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	1 (2.8)	1 (1.4)	0.997
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.515 (0.031, 8.478), 0.636	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.522 (0.034, 8.099), 0.642	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.013 (-0.074, 0.047), 0.668	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	2 (2.9)	0.951
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.302	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.029 (-0.011, 0.069), 0.151	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.6a
Summary of All Adverse Events by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Cognitive Effects AESI	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	1 (2.8)	1 (1.4)	0.997
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.515 (0.031, 8.478), 0.636	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.522 (0.034, 8.099), 0.642	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.013 (-0.074, 0.047), 0.668	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.6a
Summary of All Adverse Events by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Intracranial Bleeding AESI	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [3]
Any AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.6a
Summary of All Adverse Events by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Intracranial Bleeding AESI	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [3]
Grade 1-2 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade 1-2 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.6a
Summary of All Adverse Events by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Intracranial Bleeding AESI	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.6a
Summary of All Adverse Events by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Intracranial Bleeding AESI	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.6a
Summary of All Adverse Events by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Oedema CMQ	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [3]
Any AEs, n (%)	2 (5.7)	17 (23.6)	6 (16.7)	19 (27.5)	0.293
Odds Ratio (95% CIs) [1], P-Value		5.100 (1.107, 23.492), 0.023		1.900 (0.683, 5.287), 0.215	
Relative Risk (95% CIs) [2], P-Value		4.132 (1.010, 16.897), 0.048		1.652 (0.724, 3.769), 0.233	
Risk Difference (95% CIs) [2], P-Value		0.179 (0.054, 0.304), 0.005		0.109 (-0.052, 0.270), 0.186	
AEs Related to Study Drug, n (%)	1 (2.9)	12 (16.7)	4 (11.1)	14 (20.3)	0.325
Odds Ratio (95% CIs) [1], P-Value		6.800 (0.847, 54.590), 0.040		2.036 (0.617, 6.718), 0.236	
Relative Risk (95% CIs) [2], P-Value		5.833 (0.790, 43.086), 0.084		1.826 (0.648, 5.143), 0.254	
Risk Difference (95% CIs) [2], P-Value		0.138 (0.036, 0.240), 0.008		0.092 (-0.048, 0.232), 0.198	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.6a
Summary of All Adverse Events by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Oedema CMQ	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [3]
Grade 1-2 AEs, n (%)	2 (5.7)	17 (23.6)	6 (16.7)	19 (27.5)	0.293
Odds Ratio (95% CIs) [1], P-Value		5.100 (1.107, 23.492), 0.023		1.900 (0.683, 5.287), 0.215	
Relative Risk (95% CIs) [2], P-Value		4.132 (1.010, 16.897), 0.048		1.652 (0.724, 3.769), 0.233	
Risk Difference (95% CIs) [2], P-Value		0.179 (0.054, 0.304), 0.005		0.109 (-0.052, 0.270), 0.186	
Grade 1-2 AEs Related to Study Drug, n (%)	1 (2.9)	12 (16.7)	4 (11.1)	14 (20.3)	0.325
Odds Ratio (95% CIs) [1], P-Value		6.800 (0.847, 54.590), 0.040		2.036 (0.617, 6.718), 0.236	
Relative Risk (95% CIs) [2], P-Value		5.833 (0.790, 43.086), 0.084		1.826 (0.648, 5.143), 0.254	
Risk Difference (95% CIs) [2], P-Value		0.138 (0.036, 0.240), 0.008		0.092 (-0.048, 0.232), 0.198	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.6a
Summary of All Adverse Events by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Oedema CMQ	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	1 (1.4)	0.965
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.014 (-0.014, 0.043), 0.314	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	0	1 (1.4)	0.965
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.014 (-0.014, 0.043), 0.314	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.6a
Summary of All Adverse Events by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Oedema CMQ	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Overall	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [3]
Any AEs, n (%)	7 (100.0)	16 (84.2)	59 (92.2)	112 (91.8)	0.956
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.264		0.949 (0.310, 2.906), 0.927	
Relative Risk (95% CIs) [2], P-Value		0.842 (0.693, 1.023), 0.084		0.996 (0.911, 1.088), 0.927	
Risk Difference (95% CIs) [2], P-Value		-0.158 (-0.322, 0.006), 0.059		-0.004 (-0.086, 0.078), 0.927	
AEs Related to Study Drug, n (%)	1 (14.3)	8 (42.1)	31 (48.4)	69 (56.6)	0.346
Odds Ratio (95% CIs) [1], P-Value		4.364 (0.435, 43.724), 0.186		1.386 (0.755, 2.543), 0.291	
Relative Risk (95% CIs) [2], P-Value		2.947 (0.445, 19.502), 0.262		1.168 (0.868, 1.571), 0.306	
Risk Difference (95% CIs) [2], P-Value		0.278 (-0.063, 0.619), 0.110		0.081 (-0.070, 0.232), 0.291	
Serious AEs, n (%)	1 (14.3)	2 (10.5)	7 (10.9)	5 (4.1)	0.625
Odds Ratio (95% CIs) [1], P-Value		0.706 (0.054, 9.265), 0.790		0.348 (0.106, 1.144), 0.071	
Relative Risk (95% CIs) [2], P-Value		0.737 (0.079, 6.912), 0.789		0.375 (0.124, 1.134), 0.082	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.331, 0.256), 0.802		-0.068 (-0.153, 0.016), 0.111	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Overall	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [3]
Grade 1-2 AEs, n (%)	6 (85.7)	16 (84.2)	59 (92.2)	111 (91.0)	0.977
Odds Ratio (95% CIs) [1], P-Value		0.889 (0.077, 10.300), 0.925		0.855 (0.284, 2.577), 0.781	
Relative Risk (95% CIs) [2], P-Value		0.982 (0.686, 1.408), 0.923		0.987 (0.901, 1.081), 0.776	
Risk Difference (95% CIs) [2], P-Value		-0.015 (-0.322, 0.292), 0.923		-0.012 (-0.095, 0.071), 0.776	
Grade 1-2 AEs Related to Study Drug, n (%)	1 (14.3)	8 (42.1)	31 (48.4)	69 (56.6)	0.346
Odds Ratio (95% CIs) [1], P-Value		4.364 (0.435, 43.724), 0.186		1.386 (0.755, 2.543), 0.291	
Relative Risk (95% CIs) [2], P-Value		2.947 (0.445, 19.502), 0.262		1.168 (0.868, 1.571), 0.306	
Risk Difference (95% CIs) [2], P-Value		0.278 (-0.063, 0.619), 0.110		0.081 (-0.070, 0.232), 0.291	
Grade >=3 AEs, n (%)	2 (28.6)	4 (21.1)	13 (20.3)	26 (21.3)	0.665
Odds Ratio (95% CIs) [1], P-Value		0.667 (0.092, 4.810), 0.686		1.063 (0.503, 2.243), 0.874	
Relative Risk (95% CIs) [2], P-Value		0.737 (0.171, 3.171), 0.682		1.049 (0.580, 1.899), 0.874	
Risk Difference (95% CIs) [2], P-Value		-0.075 (-0.457, 0.306), 0.699		0.010 (-0.112, 0.132), 0.873	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	2 (3.1)	3 (2.5)	0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.782 (0.127, 4.801), 0.790	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.787 (0.135, 4.589), 0.790	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.007 (-0.057, 0.044), 0.797	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Overall	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	1 (14.3)	2 (10.5)	8 (12.5)	10 (8.2)	0.931
Odds Ratio (95% CIs) [1], P-Value		0.706 (0.054, 9.265), 0.790		0.625 (0.234, 1.671), 0.346	
Relative Risk (95% CIs) [2], P-Value		0.737 (0.079, 6.912), 0.789		0.656 (0.272, 1.579), 0.347	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.331, 0.256), 0.802		-0.043 (-0.138, 0.051), 0.372	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	1 (1.6)	2 (1.6)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.050 (0.093, 11.805), 0.968	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.049 (0.097, 11.351), 0.968	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.001 (-0.037, 0.039), 0.968	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	1 (1.6)	3 (2.5)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.588 (0.162, 15.585), 0.689	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.574 (0.167, 14.825), 0.692	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.009 (-0.032, 0.050), 0.668	
Related AEs Leading to Interruption of Study Drug, n (%)	0	1 (5.3)	4 (6.3)	4 (3.3)	0.952
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.536		0.508 (0.123, 2.104), 0.343	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.525 (0.136, 2.029), 0.350	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		-0.030 (-0.097, 0.037), 0.386	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Overall	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	1 (1.6)	1 (0.8)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.521 (0.032, 8.464), 0.641	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.525 (0.033, 8.249), 0.646	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.007 (-0.042, 0.027), 0.672	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	1 (1.6)	2 (1.6)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.050 (0.093, 11.805), 0.968	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.049 (0.097, 11.351), 0.968	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.001 (-0.037, 0.039), 0.968	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Cognitive Effects AESI	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [3]
Any AEs, n (%)	0	1 (5.3)	3 (4.7)	3 (2.5)	0.957
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.536		0.513 (0.100, 2.616), 0.414	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.525 (0.109, 2.525), 0.421	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		-0.022 (-0.081, 0.036), 0.456	
AEs Related to Study Drug, n (%)	0	1 (5.3)	2 (3.1)	2 (1.6)	0.962
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.536		0.517 (0.071, 3.756), 0.507	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.525 (0.076, 3.638), 0.514	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		-0.015 (-0.063, 0.033), 0.546	
Serious AEs, n (%)	0	0	1 (1.6)	0	0.980
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.166	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.016 (-0.046, 0.015), 0.313	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Cognitive Effects AESI	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [3]
Grade 1-2 AEs, n (%)	0	1 (5.3)	2 (3.1)	3 (2.5)	0.961
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.536		0.782 (0.127, 4.801), 0.790	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.787 (0.135, 4.589), 0.790	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		-0.007 (-0.057, 0.044), 0.797	
Grade 1-2 AEs Related to Study Drug, n (%)	0	1 (5.3)	2 (3.1)	2 (1.6)	0.962
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.536		0.517 (0.071, 3.756), 0.507	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.525 (0.076, 3.638), 0.514	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		-0.015 (-0.063, 0.033), 0.546	
Grade >=3 AEs, n (%)	0	0	1 (1.6)	0	0.980
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.166	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.016 (-0.046, 0.015), 0.313	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Cognitive Effects AESI	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	1 (5.3)	0	1 (0.8)	0.997
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.536		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		0.008 (-0.008, 0.024), 0.315	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	1 (1.6)	1 (0.8)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.521 (0.032, 8.464), 0.641	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.525 (0.033, 8.249), 0.646	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.007 (-0.042, 0.027), 0.672	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	1 (5.3)	0	1 (0.8)	0.997
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.536		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		0.008 (-0.008, 0.024), 0.315	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Cognitive Effects AESI	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	1 (1.6)	1 (0.8)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.521 (0.032, 8.464), 0.641	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.525 (0.033, 8.249), 0.646	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.007 (-0.042, 0.027), 0.672	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Intracranial Bleeding AESI	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [3]
Any AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Intracranial Bleeding AESI	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [3]
Grade 1-2 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade 1-2 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Intracranial Bleeding AESI	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Intracranial Bleeding AESI	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Oedema CMQ	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [3]
Any AEs, n (%)	0	5 (26.3)	8 (12.5)	31 (25.4)	0.960
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.131		2.385 (1.024, 5.554), 0.040	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.033 (0.993, 4.159), 0.052	
Risk Difference (95% CIs) [2], P-Value		0.263 (0.065, 0.461), 0.009		0.129 (0.017, 0.241), 0.024	
AEs Related to Study Drug, n (%)	0	2 (10.5)	5 (7.8)	24 (19.7)	0.954
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.372		2.890 (1.046, 7.984), 0.034	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.518 (1.009, 6.286), 0.048	
Risk Difference (95% CIs) [2], P-Value		0.105 (-0.033, 0.243), 0.135		0.119 (0.022, 0.215), 0.016	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Oedema CMQ	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [3]
Grade 1-2 AEs, n (%)	0	5 (26.3)	8 (12.5)	31 (25.4)	0.960
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.131		2.385 (1.024, 5.554), 0.040	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.033 (0.993, 4.159), 0.052	
Risk Difference (95% CIs) [2], P-Value		0.263 (0.065, 0.461), 0.009		0.129 (0.017, 0.241), 0.024	
Grade 1-2 AEs Related to Study Drug, n (%)	0	2 (10.5)	5 (7.8)	24 (19.7)	0.954
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.372		2.890 (1.046, 7.984), 0.034	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.518 (1.009, 6.286), 0.048	
Risk Difference (95% CIs) [2], P-Value		0.105 (-0.033, 0.243), 0.135		0.119 (0.022, 0.215), 0.016	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Oedema CMQ	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	1 (0.8)	0.981
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.008 (-0.008, 0.024), 0.315	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	0	1 (0.8)	0.981
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.008 (-0.008, 0.024), 0.315	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.7a
Summary of All Adverse Events by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Oedema CMQ	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.8a
Summary of All Adverse Events by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Overall	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [3]
Any AEs, n (%)	11 (100.0)	24 (92.3)	55 (91.7)	104 (90.4)	0.950
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.344		0.860 (0.284, 2.599), 0.788	
Relative Risk (95% CIs) [2], P-Value		0.923 (0.826, 1.031), 0.157		0.987 (0.896, 1.087), 0.784	
Risk Difference (95% CIs) [2], P-Value		-0.077 (-0.179, 0.026), 0.141		-0.012 (-0.101, 0.076), 0.784	
AEs Related to Study Drug, n (%)	6 (54.5)	16 (61.5)	26 (43.3)	61 (53.0)	0.897
Odds Ratio (95% CIs) [1], P-Value		1.333 (0.320, 5.548), 0.692		1.477 (0.788, 2.769), 0.223	
Relative Risk (95% CIs) [2], P-Value		1.128 (0.607, 2.095), 0.703		1.224 (0.874, 1.714), 0.239	
Risk Difference (95% CIs) [2], P-Value		0.070 (-0.279, 0.419), 0.694		0.097 (-0.058, 0.252), 0.220	
Serious AEs, n (%)	0	3 (11.5)	8 (13.3)	4 (3.5)	0.944
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.240		0.234 (0.067, 0.813), 0.014	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.261 (0.082, 0.831), 0.023	
Risk Difference (95% CIs) [2], P-Value		0.115 (-0.007, 0.238), 0.066		-0.099 (-0.191, -0.006), 0.036	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.8a
Summary of All Adverse Events by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Overall	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [3]
Grade 1-2 AEs, n (%)	11 (100.0)	24 (92.3)	54 (90.0)	103 (89.6)	0.947
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.344		0.954 (0.339, 2.682), 0.928	
Relative Risk (95% CIs) [2], P-Value		0.923 (0.826, 1.031), 0.157		0.995 (0.896, 1.105), 0.928	
Risk Difference (95% CIs) [2], P-Value		-0.077 (-0.179, 0.026), 0.141		-0.004 (-0.099, 0.090), 0.928	
Grade 1-2 AEs Related to Study Drug, n (%)	6 (54.5)	16 (61.5)	26 (43.3)	61 (53.0)	0.897
Odds Ratio (95% CIs) [1], P-Value		1.333 (0.320, 5.548), 0.692		1.477 (0.788, 2.769), 0.223	
Relative Risk (95% CIs) [2], P-Value		1.128 (0.607, 2.095), 0.703		1.224 (0.874, 1.714), 0.239	
Risk Difference (95% CIs) [2], P-Value		0.070 (-0.279, 0.419), 0.694		0.097 (-0.058, 0.252), 0.220	
Grade >=3 AEs, n (%)	0	8 (30.8)	15 (25.0)	22 (19.1)	0.943
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.038		0.710 (0.336, 1.497), 0.367	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.765 (0.430, 1.363), 0.364	
Risk Difference (95% CIs) [2], P-Value		0.308 (0.130, 0.485), <0.001		-0.059 (-0.190, 0.072), 0.380	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	2 (3.3)	3 (2.6)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.777 (0.126, 4.780), 0.785	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.783 (0.134, 4.557), 0.785	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.007 (-0.061, 0.047), 0.792	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.8a
Summary of All Adverse Events by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Overall	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	3 (11.5)	9 (15.0)	9 (7.8)	0.940
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.240		0.481 (0.180, 1.285), 0.138	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.522 (0.219, 1.245), 0.143	
Risk Difference (95% CIs) [2], P-Value		0.115 (-0.007, 0.238), 0.066		-0.072 (-0.175, 0.031), 0.171	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	1 (1.7)	2 (1.7)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.044 (0.093, 11.755), 0.972	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.043 (0.097, 11.276), 0.972	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.001 (-0.040, 0.041), 0.972	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	1 (1.7)	3 (2.6)	0.997
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.580 (0.161, 15.529), 0.692	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.565 (0.166, 14.725), 0.695	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.009 (-0.034, 0.053), 0.672	
Related AEs Leading to Interruption of Study Drug, n (%)	0	2 (7.7)	4 (6.7)	3 (2.6)	0.958
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.344		0.375 (0.081, 1.733), 0.193	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.391 (0.091, 1.692), 0.209	
Risk Difference (95% CIs) [2], P-Value		0.077 (-0.026, 0.179), 0.141		-0.041 (-0.110, 0.029), 0.253	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.8a
Summary of All Adverse Events by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Overall	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	1 (1.7)	1 (0.9)	0.997
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.518 (0.032, 8.423), 0.638	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.522 (0.033, 8.196), 0.643	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.008 (-0.045, 0.029), 0.669	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	1 (1.7)	2 (1.7)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.044 (0.093, 11.755), 0.972	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.043 (0.097, 11.276), 0.972	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.001 (-0.040, 0.041), 0.972	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.8a
Summary of All Adverse Events by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Cognitive Effects AESI	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [3]
Any AEs, n (%)	0	1 (3.8)	3 (5.0)	3 (2.6)	0.948
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.510		0.509 (0.100, 2.602), 0.409	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.522 (0.109, 2.507), 0.417	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.035, 0.112), 0.308		-0.024 (-0.086, 0.038), 0.452	
AEs Related to Study Drug, n (%)	0	1 (3.8)	2 (3.3)	2 (1.7)	0.954
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.510		0.513 (0.070, 3.738), 0.503	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.522 (0.075, 3.612), 0.510	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.035, 0.112), 0.308		-0.016 (-0.067, 0.035), 0.543	
Serious AEs, n (%)	0	0	1 (1.7)	0	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.165	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.017 (-0.049, 0.016), 0.313	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.8a
Summary of All Adverse Events by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Cognitive Effects AESI	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [3]
Grade 1-2 AEs, n (%)	0	1 (3.8)	2 (3.3)	3 (2.6)	0.953
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.510		0.777 (0.126, 4.780), 0.785	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.783 (0.134, 4.557), 0.785	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.035, 0.112), 0.308		-0.007 (-0.061, 0.047), 0.792	
Grade 1-2 AEs Related to Study Drug, n (%)	0	1 (3.8)	2 (3.3)	2 (1.7)	0.954
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.510		0.513 (0.070, 3.738), 0.503	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.522 (0.075, 3.612), 0.510	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.035, 0.112), 0.308		-0.016 (-0.067, 0.035), 0.543	
Grade >=3 AEs, n (%)	0	0	1 (1.7)	0	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.165	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.017 (-0.049, 0.016), 0.313	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.8a
Summary of All Adverse Events by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Cognitive Effects AESI	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	1 (3.8)	0	1 (0.9)	0.998
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.510		NE (NE, NE), 0.469	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.035, 0.112), 0.308		0.009 (-0.008, 0.026), 0.315	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	1 (1.7)	1 (0.9)	0.997
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.518 (0.032, 8.423), 0.638	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.522 (0.033, 8.196), 0.643	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.008 (-0.045, 0.029), 0.669	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	1 (3.8)	0	1 (0.9)	0.998
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.510		NE (NE, NE), 0.469	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.035, 0.112), 0.308		0.009 (-0.008, 0.026), 0.315	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.8a
Summary of All Adverse Events by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Cognitive Effects AESI	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	1 (1.7)	1 (0.9)	0.997
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.518 (0.032, 8.423), 0.638	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.522 (0.033, 8.196), 0.643	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.008 (-0.045, 0.029), 0.669	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.8a
Summary of All Adverse Events by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Intracranial Bleeding AESI	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [3]
Any AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.8a
Summary of All Adverse Events by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Intracranial Bleeding AESI	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [3]
Grade 1-2 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade 1-2 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.8a
Summary of All Adverse Events by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Intracranial Bleeding AESI	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.8a
Summary of All Adverse Events by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Intracranial Bleeding AESI	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.8a
Summary of All Adverse Events by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Oedema CMQ	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [3]
Any AEs, n (%)	2 (18.2)	6 (23.1)	6 (10.0)	30 (26.1)	0.406
Odds Ratio (95% CIs) [1], P-Value		1.350 (0.227, 8.031), 0.741		3.176 (1.240, 8.136), 0.012	
Relative Risk (95% CIs) [2], P-Value		1.269 (0.302, 5.339), 0.745		2.609 (1.150, 5.917), 0.022	
Risk Difference (95% CIs) [2], P-Value		0.049 (-0.231, 0.329), 0.731		0.161 (0.050, 0.271), 0.004	
AEs Related to Study Drug, n (%)	2 (18.2)	3 (11.5)	3 (5.0)	23 (20.0)	0.076
Odds Ratio (95% CIs) [1], P-Value		0.587 (0.084, 4.118), 0.589		4.750 (1.364, 16.540), 0.008	
Relative Risk (95% CIs) [2], P-Value		0.635 (0.123, 3.286), 0.588		4.000 (1.252, 12.784), 0.019	
Risk Difference (95% CIs) [2], P-Value		-0.066 (-0.325, 0.192), 0.615		0.150 (0.058, 0.242), 0.001	
Serious AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Serious AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.8a
Summary of All Adverse Events by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Oedema CMQ	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [3]
Grade 1-2 AEs, n (%)	2 (18.2)	6 (23.1)	6 (10.0)	30 (26.1)	0.406
Odds Ratio (95% CIs) [1], P-Value		1.350 (0.227, 8.031), 0.741		3.176 (1.240, 8.136), 0.012	
Relative Risk (95% CIs) [2], P-Value		1.269 (0.302, 5.339), 0.745		2.609 (1.150, 5.917), 0.022	
Risk Difference (95% CIs) [2], P-Value		0.049 (-0.231, 0.329), 0.731		0.161 (0.050, 0.271), 0.004	
Grade 1-2 AEs Related to Study Drug, n (%)	2 (18.2)	3 (11.5)	3 (5.0)	23 (20.0)	0.076
Odds Ratio (95% CIs) [1], P-Value		0.587 (0.084, 4.118), 0.589		4.750 (1.364, 16.540), 0.008	
Relative Risk (95% CIs) [2], P-Value		0.635 (0.123, 3.286), 0.588		4.000 (1.252, 12.784), 0.019	
Risk Difference (95% CIs) [2], P-Value		-0.066 (-0.325, 0.192), 0.615		0.150 (0.058, 0.242), 0.001	
Grade >=3 AEs, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Grade >=3 AEs Related to Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.8a
Summary of All Adverse Events by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Oedema CMQ	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [3]
AEs Leading to Interruption of Study Drug Regardless of Causality, n (%)	0	0	0	1 (0.9)	0.977
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.469	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.009 (-0.008, 0.026), 0.315	
AEs Leading to Reduction of Study Drug Regardless of Causality, n (%)	0	0	0	1 (0.9)	0.977
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.469	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.009 (-0.008, 0.026), 0.315	
AEs Leading to Permanent Discontinuation of Study Drug Regardless of Causality, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Interruption of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.1.1.8a
Summary of All Adverse Events by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Oedema CMQ	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [3]
Related AEs Leading to Reduction of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Related AEs Leading to Permanent Discontinuation of Study Drug, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
AE leading to Death, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note: All Adverse Events are Treatment Emergent Adverse Events. Treatment Emergent AE is defined as any AE that occurred between the Part 2 D1 through a day prior to Part 3 D1, or through 30 days after the last dose if patient do not rollover to part 3.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-sum-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.2.1.1.1a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Gastrointestinal disorders, n (%)	13 (21.7)	26 (19.7)	3 (27.3)	1 (11.1)	0.457
Odds Ratio (95% CIs) [1], P-Value		0.887 (0.419, 1.876), 0.753		0.333 (0.028, 3.926), 0.369	
Relative Risk (95% CIs) [2], P-Value		0.909 (0.503, 1.643), 0.752		0.407 (0.051, 3.276), 0.399	
Risk Difference (95% CIs) [2], P-Value		-0.020 (-0.144, 0.105), 0.756		-0.162 (-0.495, 0.172), 0.343	
Nausea, n (%)	9 (15.0)	17 (12.9)	3 (27.3)	1 (11.1)	0.490
Odds Ratio (95% CIs) [1], P-Value		0.838 (0.350, 2.005), 0.691		0.333 (0.028, 3.926), 0.369	
Relative Risk (95% CIs) [2], P-Value		0.859 (0.406, 1.814), 0.690		0.407 (0.051, 3.276), 0.399	
Risk Difference (95% CIs) [2], P-Value		-0.021 (-0.128, 0.086), 0.697		-0.162 (-0.495, 0.172), 0.343	
Diarrhoea, n (%)	6 (10.0)	15 (11.4)	2 (18.2)	0	0.944
Odds Ratio (95% CIs) [1], P-Value		1.154 (0.424, 3.137), 0.779		NE (NE, NE), 0.178	
Relative Risk (95% CIs) [2], P-Value		1.136 (0.464, 2.784), 0.780		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.014 (-0.080, 0.107), 0.774		-0.182 (-0.410, 0.046), 0.118	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.2.1.1.1a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Infections and infestations, n (%)	7 (11.7)	16 (12.1)	1 (9.1)	1 (11.1)	0.909
Odds Ratio (95% CIs) [1], P-Value		1.044 (0.406, 2.689), 0.928		1.250 (0.067, 23.259), 0.881	
Relative Risk (95% CIs) [2], P-Value		1.039 (0.451, 2.392), 0.928		1.222 (0.088, 16.924), 0.881	
Risk Difference (95% CIs) [2], P-Value		0.005 (-0.094, 0.103), 0.928		0.020 (-0.246, 0.287), 0.882	
COVID-19, n (%)	7 (11.7)	16 (12.1)	1 (9.1)	1 (11.1)	0.909
Odds Ratio (95% CIs) [1], P-Value		1.044 (0.406, 2.689), 0.928		1.250 (0.067, 23.259), 0.881	
Relative Risk (95% CIs) [2], P-Value		1.039 (0.451, 2.392), 0.928		1.222 (0.088, 16.924), 0.881	
Risk Difference (95% CIs) [2], P-Value		0.005 (-0.094, 0.103), 0.928		0.020 (-0.246, 0.287), 0.882	
Nervous system disorders, n (%)	13 (21.7)	37 (28.0)	4 (36.4)	1 (11.1)	0.148
Odds Ratio (95% CIs) [1], P-Value		1.408 (0.684, 2.899), 0.352		0.219 (0.020, 2.447), 0.194	
Relative Risk (95% CIs) [2], P-Value		1.294 (0.744, 2.250), 0.362		0.306 (0.041, 2.272), 0.247	
Risk Difference (95% CIs) [2], P-Value		0.064 (-0.066, 0.193), 0.335		-0.253 (-0.603, 0.098), 0.158	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.2.1.1.1a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Nervous system disorders (cont.)					
Headache, n (%)	11 (18.3)	26 (19.7)	3 (27.3)	1 (11.1)	0.368
Odds Ratio (95% CIs) [1], P-Value		1.093 (0.500, 2.388), 0.824		0.333 (0.028, 3.926), 0.369	
Relative Risk (95% CIs) [2], P-Value		1.074 (0.569, 2.028), 0.825		0.407 (0.051, 3.276), 0.399	
Risk Difference (95% CIs) [2], P-Value		0.014 (-0.105, 0.133), 0.822		-0.162 (-0.495, 0.172), 0.343	
Dizziness, n (%)	5 (8.3)	16 (12.1)	1 (9.1)	0	0.948
Odds Ratio (95% CIs) [1], P-Value		1.517 (0.529, 4.354), 0.436		NE (NE, NE), 0.353	
Relative Risk (95% CIs) [2], P-Value		1.455 (0.559, 3.786), 0.443		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.052, 0.127), 0.406		-0.091 (-0.261, 0.079), 0.294	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.2.1.1.2a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Gastrointestinal disorders, n (%)	4 (23.5)	9 (22.0)	12 (22.2)	18 (18.0)	0.829
Odds Ratio (95% CIs) [1], P-Value		0.914 (0.239, 3.500), 0.896		0.768 (0.338, 1.744), 0.528	
Relative Risk (95% CIs) [2], P-Value		0.933 (0.332, 2.622), 0.895		0.810 (0.422, 1.553), 0.526	
Risk Difference (95% CIs) [2], P-Value		-0.016 (-0.254, 0.222), 0.897		-0.042 (-0.176, 0.092), 0.537	
Nausea, n (%)	4 (23.5)	7 (17.1)	8 (14.8)	11 (11.0)	0.944
Odds Ratio (95% CIs) [1], P-Value		0.669 (0.168, 2.672), 0.568		0.711 (0.267, 1.889), 0.492	
Relative Risk (95% CIs) [2], P-Value		0.726 (0.244, 2.160), 0.564		0.743 (0.318, 1.734), 0.492	
Risk Difference (95% CIs) [2], P-Value		-0.065 (-0.297, 0.168), 0.586		-0.038 (-0.151, 0.075), 0.508	
Diarrhoea, n (%)	1 (5.9)	3 (7.3)	7 (13.0)	12 (12.0)	0.804
Odds Ratio (95% CIs) [1], P-Value		1.263 (0.122, 13.078), 0.844		0.916 (0.338, 2.482), 0.862	
Relative Risk (95% CIs) [2], P-Value		1.244 (0.139, 11.130), 0.845		0.926 (0.387, 2.213), 0.862	
Risk Difference (95% CIs) [2], P-Value		0.014 (-0.123, 0.152), 0.838		-0.010 (-0.120, 0.100), 0.864	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.2.1.1.2a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Infections and infestations, n (%)	4 (23.5)	5 (12.2)	4 (7.4)	12 (12.0)	0.166
Odds Ratio (95% CIs) [1], P-Value		0.451 (0.105, 1.943), 0.278		1.705 (0.522, 5.567), 0.373	
Relative Risk (95% CIs) [2], P-Value		0.518 (0.158, 1.699), 0.278		1.620 (0.549, 4.780), 0.382	
Risk Difference (95% CIs) [2], P-Value		-0.113 (-0.338, 0.112), 0.324		0.046 (-0.049, 0.140), 0.341	
COVID-19, n (%)	4 (23.5)	5 (12.2)	4 (7.4)	12 (12.0)	0.166
Odds Ratio (95% CIs) [1], P-Value		0.451 (0.105, 1.943), 0.278		1.705 (0.522, 5.567), 0.373	
Relative Risk (95% CIs) [2], P-Value		0.518 (0.158, 1.699), 0.278		1.620 (0.549, 4.780), 0.382	
Risk Difference (95% CIs) [2], P-Value		-0.113 (-0.338, 0.112), 0.324		0.046 (-0.049, 0.140), 0.341	
Nervous system disorders, n (%)	0	10 (24.4)	17 (31.5)	28 (28.0)	0.953
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.025		0.846 (0.411, 1.741), 0.650	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.889 (0.538, 1.472), 0.648	
Risk Difference (95% CIs) [2], P-Value		0.244 (0.112, 0.375), <0.001		-0.035 (-0.187, 0.117), 0.653	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.2.1.1.2a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Nervous system disorders (cont.)					
Headache, n (%)	0	9 (22.0)	14 (25.9)	18 (18.0)	0.934
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.036		0.627 (0.283, 1.388), 0.247	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.694 (0.375, 1.284), 0.245	
Risk Difference (95% CIs) [2], P-Value		0.220 (0.093, 0.346), <0.001		-0.079 (-0.218, 0.060), 0.264	
Dizziness, n (%)	0	4 (9.8)	6 (11.1)	12 (12.0)	0.954
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.182		1.091 (0.385, 3.090), 0.870	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.080 (0.429, 2.717), 0.870	
Risk Difference (95% CIs) [2], P-Value		0.098 (0.007, 0.188), 0.035		0.009 (-0.096, 0.114), 0.869	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.2.1.1.3a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Gastrointestinal disorders, n (%)	7 (21.2)	9 (15.0)	9 (23.7)	18 (22.2)	0.640
Odds Ratio (95% CIs) [1], P-Value		0.655 (0.219, 1.959), 0.448		0.921 (0.369, 2.294), 0.859	
Relative Risk (95% CIs) [2], P-Value		0.707 (0.290, 1.725), 0.446		0.938 (0.465, 1.892), 0.859	
Risk Difference (95% CIs) [2], P-Value		-0.062 (-0.228, 0.104), 0.464		-0.015 (-0.177, 0.148), 0.860	
Nausea, n (%)	5 (15.2)	7 (11.7)	7 (18.4)	11 (13.6)	0.941
Odds Ratio (95% CIs) [1], P-Value		0.740 (0.215, 2.545), 0.631		0.696 (0.247, 1.964), 0.492	
Relative Risk (95% CIs) [2], P-Value		0.770 (0.265, 2.236), 0.631		0.737 (0.310, 1.752), 0.490	
Risk Difference (95% CIs) [2], P-Value		-0.035 (-0.182, 0.112), 0.642		-0.048 (-0.192, 0.096), 0.510	
Diarrhoea, n (%)	4 (12.1)	5 (8.3)	4 (10.5)	10 (12.3)	0.528
Odds Ratio (95% CIs) [1], P-Value		0.659 (0.164, 2.645), 0.554		1.197 (0.350, 4.094), 0.774	
Relative Risk (95% CIs) [2], P-Value		0.687 (0.198, 2.386), 0.555		1.173 (0.393, 3.501), 0.775	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.169, 0.094), 0.572		0.018 (-0.103, 0.139), 0.768	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.2.1.1.3a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Infections and infestations, n (%)	3 (9.1)	4 (6.7)	5 (13.2)	13 (16.0)	0.561
Odds Ratio (95% CIs) [1], P-Value		0.714 (0.150, 3.403), 0.672		1.262 (0.415, 3.837), 0.681	
Relative Risk (95% CIs) [2], P-Value		0.733 (0.175, 3.081), 0.672		1.220 (0.469, 3.175), 0.684	
Risk Difference (95% CIs) [2], P-Value		-0.024 (-0.141, 0.092), 0.684		0.029 (-0.105, 0.163), 0.672	
COVID-19, n (%)	3 (9.1)	4 (6.7)	5 (13.2)	13 (16.0)	0.561
Odds Ratio (95% CIs) [1], P-Value		0.714 (0.150, 3.403), 0.672		1.262 (0.415, 3.837), 0.681	
Relative Risk (95% CIs) [2], P-Value		0.733 (0.175, 3.081), 0.672		1.220 (0.469, 3.175), 0.684	
Risk Difference (95% CIs) [2], P-Value		-0.024 (-0.141, 0.092), 0.684		0.029 (-0.105, 0.163), 0.672	
Nervous system disorders, n (%)	7 (21.2)	18 (30.0)	10 (26.3)	20 (24.7)	0.419
Odds Ratio (95% CIs) [1], P-Value		1.592 (0.585, 4.330), 0.360		0.918 (0.380, 2.216), 0.849	
Relative Risk (95% CIs) [2], P-Value		1.414 (0.660, 3.032), 0.373		0.938 (0.488, 1.804), 0.849	
Risk Difference (95% CIs) [2], P-Value		0.088 (-0.094, 0.269), 0.342		-0.016 (-0.185, 0.152), 0.850	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.2.1.1.3a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Nervous system disorders (cont.)					
Headache, n (%)	7 (21.2)	14 (23.3)	7 (18.4)	13 (16.0)	0.694
Odds Ratio (95% CIs) [1], P-Value		1.130 (0.405, 3.156), 0.815		0.847 (0.308, 2.330), 0.747	
Relative Risk (95% CIs) [2], P-Value		1.100 (0.493, 2.452), 0.816		0.871 (0.378, 2.006), 0.746	
Risk Difference (95% CIs) [2], P-Value		0.021 (-0.155, 0.197), 0.813		-0.024 (-0.171, 0.123), 0.752	
Dizziness, n (%)	1 (3.0)	6 (10.0)	5 (13.2)	10 (12.3)	0.283
Odds Ratio (95% CIs) [1], P-Value		3.556 (0.409, 30.883), 0.223		0.930 (0.294, 2.936), 0.901	
Relative Risk (95% CIs) [2], P-Value		3.300 (0.415, 26.255), 0.259		0.938 (0.344, 2.555), 0.901	
Risk Difference (95% CIs) [2], P-Value		0.070 (-0.026, 0.166), 0.154		-0.008 (-0.137, 0.121), 0.902	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.2.1.1.9a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Gastrointestinal disorders, n (%)	5 (17.9)	7 (13.5)	4 (26.7)	4 (21.1)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nausea, n (%)	4 (14.3)	5 (9.6)	4 (26.7)	3 (15.8)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Diarrhoea, n (%)	2 (7.1)	4 (7.7)	1 (6.7)	1 (5.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Infections and infestations, n (%)	2 (7.1)	3 (5.8)	1 (6.7)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.9a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Gastrointestinal disorders, n (%)	1 (16.7)	2 (18.2)	0	2 (14.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nausea, n (%)	1 (16.7)	0	0	1 (7.1)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Diarrhoea, n (%)	0	2 (18.2)	0	2 (14.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Infections and infestations, n (%)	0	0	0	3 (21.4)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.9a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Gastrointestinal disorders, n (%)	1 (20.0)	3 (27.3)	2 (40.0)	2 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nausea, n (%)	0	2 (18.2)	1 (20.0)	2 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Diarrhoea, n (%)	1 (20.0)	2 (18.2)	2 (40.0)	1 (12.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Infections and infestations, n (%)	2 (40.0)	2 (18.2)	1 (20.0)	1 (12.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.9a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Gastrointestinal disorders, n (%)	0	3 (33.3)	2 (66.7)	2 (40.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nausea, n (%)	0	1 (11.1)	2 (66.7)	2 (40.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Diarrhoea, n (%)	0	2 (22.2)	1 (33.3)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Infections and infestations, n (%)	0	2 (22.2)	1 (33.3)	3 (60.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.9a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Gastrointestinal disorders, n (%)	0	1 (33.3)	0	1 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nausea, n (%)	0	1 (33.3)	0	1 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Diarrhoea, n (%)	0	0	0	1 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Infections and infestations, n (%)	0	1 (33.3)	0	1 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.9a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden		Switzerland	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=2)
Gastrointestinal disorders, n (%)	0	0	1 (100.0)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nausea, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Diarrhoea, n (%)	0	0	1 (100.0)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Infections and infestations, n (%)	1 (100.0)	1 (50.0)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.9a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Gastrointestinal disorders, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Nausea, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Diarrhoea, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Infections and infestations, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.9a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Infections and infestations (cont.)	2 (7.1)	3 (5.8)	1 (6.7)	0
COVID-19, n (%)	2 (7.1)	3 (5.8)	1 (6.7)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nervous system disorders, n (%)	4 (14.3)	16 (30.8)	5 (33.3)	5 (26.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Headache, n (%)	4 (14.3)	12 (23.1)	3 (20.0)	3 (15.8)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dizziness, n (%)	1 (3.6)	6 (11.5)	3 (20.0)	3 (15.8)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.9a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Infections and infestations (cont.)	0	0	0	3 (21.4)
COVID-19, n (%)	0	0	0	3 (21.4)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nervous system disorders, n (%)	1 (16.7)	1 (9.1)	0	4 (28.6)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Headache, n (%)	1 (16.7)	1 (9.1)	0	3 (21.4)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dizziness, n (%)	0	0	0	1 (7.1)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.9a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Infections and infestations (cont.)	2 (40.0)	2 (18.2)	1 (20.0)	1 (12.5)
COVID-19, n (%)	2 (40.0)	2 (18.2)	1 (20.0)	1 (12.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nervous system disorders, n (%)	2 (40.0)	1 (9.1)	3 (60.0)	2 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Headache, n (%)	1 (20.0)	1 (9.1)	3 (60.0)	2 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dizziness, n (%)	2 (40.0)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.9a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Infections and infestations (cont.)	0	2 (22.2)	1 (33.3)	3 (60.0)
COVID-19, n (%)	0	2 (22.2)	1 (33.3)	3 (60.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nervous system disorders, n (%)	0	3 (33.3)	1 (33.3)	2 (40.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Headache, n (%)	0	1 (11.1)	1 (33.3)	2 (40.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dizziness, n (%)	0	3 (33.3)	0	1 (20.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.9a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Infections and infestations (cont.)	0	1 (33.3)	0	1 (25.0)
COVID-19, n (%)	0	1 (33.3)	0	1 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nervous system disorders, n (%)	0	2 (66.7)	0	1 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Headache, n (%)	0	2 (66.7)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dizziness, n (%)	0	0	0	1 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.9a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=2)	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)
Infections and infestations (cont.)	1 (100.0)	1 (50.0)	0	0
COVID-19, n (%)	1 (100.0)	1 (50.0)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nervous system disorders, n (%)	0	0	1 (100.0)	1 (50.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Headache, n (%)	0	0	1 (100.0)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dizziness, n (%)	0	0	0	1 (50.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.9a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Infections and infestations (cont.)	0	0	-
COVID-19, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Nervous system disorders, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Headache, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Dizziness, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.4a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Gastrointestinal disorders, n (%)	7 (26.9)	9 (17.3)	9 (20.0)	18 (20.7)	0.407
Odds Ratio (95% CIs) [1], P-Value		0.568 (0.184, 1.751), 0.321		1.043 (0.426, 2.556), 0.926	
Relative Risk (95% CIs) [2], P-Value		0.643 (0.270, 1.532), 0.319		1.034 (0.506, 2.114), 0.926	
Risk Difference (95% CIs) [2], P-Value		-0.096 (-0.295, 0.103), 0.344		0.007 (-0.138, 0.151), 0.926	
Nausea, n (%)	6 (23.1)	5 (9.6)	6 (13.3)	13 (14.9)	0.168
Odds Ratio (95% CIs) [1], P-Value		0.355 (0.097, 1.297), 0.107		1.142 (0.403, 3.238), 0.803	
Relative Risk (95% CIs) [2], P-Value		0.417 (0.140, 1.239), 0.115		1.121 (0.457, 2.751), 0.804	
Risk Difference (95% CIs) [2], P-Value		-0.135 (-0.315, 0.046), 0.144		0.016 (-0.108, 0.140), 0.800	
Diarrhoea, n (%)	4 (15.4)	5 (9.6)	4 (8.9)	10 (11.5)	0.387
Odds Ratio (95% CIs) [1], P-Value		0.585 (0.143, 2.394), 0.452		1.331 (0.393, 4.508), 0.645	
Relative Risk (95% CIs) [2], P-Value		0.625 (0.183, 2.133), 0.453		1.293 (0.429, 3.894), 0.648	
Risk Difference (95% CIs) [2], P-Value		-0.058 (-0.218, 0.102), 0.480		0.026 (-0.081, 0.133), 0.633	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.2.1.1.4a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Infections and infestations, n (%)	1 (3.8)	3 (5.8)	7 (15.6)	14 (16.1)	0.764
Odds Ratio (95% CIs) [1], P-Value		1.531 (0.151, 15.480), 0.717		1.041 (0.387, 2.797), 0.936	
Relative Risk (95% CIs) [2], P-Value		1.500 (0.164, 13.724), 0.720		1.034 (0.450, 2.379), 0.936	
Risk Difference (95% CIs) [2], P-Value		0.019 (-0.078, 0.117), 0.699		0.005 (-0.126, 0.136), 0.936	
COVID-19, n (%)	1 (3.8)	3 (5.8)	7 (15.6)	14 (16.1)	0.764
Odds Ratio (95% CIs) [1], P-Value		1.531 (0.151, 15.480), 0.717		1.041 (0.387, 2.797), 0.936	
Relative Risk (95% CIs) [2], P-Value		1.500 (0.164, 13.724), 0.720		1.034 (0.450, 2.379), 0.936	
Risk Difference (95% CIs) [2], P-Value		0.019 (-0.078, 0.117), 0.699		0.005 (-0.126, 0.136), 0.936	
Nervous system disorders, n (%)	6 (23.1)	12 (23.1)	11 (24.4)	26 (29.9)	0.697
Odds Ratio (95% CIs) [1], P-Value		1.000 (0.327, 3.057), >0.999		1.317 (0.580, 2.992), 0.509	
Relative Risk (95% CIs) [2], P-Value		1.000 (0.423, 2.362), >0.999		1.223 (0.667, 2.241), 0.516	
Risk Difference (95% CIs) [2], P-Value		0.000 (-0.198, 0.198), >0.999		0.054 (-0.104, 0.213), 0.500	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.2.1.1.4a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Nervous system disorders (cont.)					
Headache, n (%)	5 (19.2)	8 (15.4)	9 (20.0)	19 (21.8)	0.624
Odds Ratio (95% CIs) [1], P-Value		0.764 (0.223, 2.619), 0.667		1.118 (0.459, 2.722), 0.806	
Relative Risk (95% CIs) [2], P-Value		0.800 (0.290, 2.204), 0.666		1.092 (0.539, 2.214), 0.807	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.219, 0.142), 0.676		0.018 (-0.127, 0.164), 0.804	
Dizziness, n (%)	1 (3.8)	6 (11.5)	5 (11.1)	10 (11.5)	0.361
Odds Ratio (95% CIs) [1], P-Value		3.261 (0.371, 28.625), 0.262		1.039 (0.332, 3.247), 0.948	
Relative Risk (95% CIs) [2], P-Value		3.000 (0.381, 23.632), 0.297		1.034 (0.376, 2.844), 0.948	
Risk Difference (95% CIs) [2], P-Value		0.077 (-0.037, 0.191), 0.186		0.004 (-0.110, 0.118), 0.947	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.2.1.1.5a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Gastrointestinal disorders, n (%)	4 (26.7)	8 (28.6)	12 (21.4)	19 (16.8)	0.633
Odds Ratio (95% CIs) [1], P-Value		1.100 (0.269, 4.496), 0.894		0.741 (0.331, 1.660), 0.466	
Relative Risk (95% CIs) [2], P-Value		1.071 (0.385, 2.981), 0.895		0.785 (0.411, 1.500), 0.463	
Risk Difference (95% CIs) [2], P-Value		0.019 (-0.260, 0.298), 0.894		-0.046 (-0.174, 0.082), 0.479	
Nausea, n (%)	3 (20.0)	7 (25.0)	9 (16.1)	11 (9.7)	0.347
Odds Ratio (95% CIs) [1], P-Value		1.333 (0.290, 6.140), 0.711		0.563 (0.219, 1.451), 0.230	
Relative Risk (95% CIs) [2], P-Value		1.250 (0.377, 4.143), 0.715		0.606 (0.267, 1.376), 0.231	
Risk Difference (95% CIs) [2], P-Value		0.050 (-0.208, 0.308), 0.704		-0.063 (-0.174, 0.047), 0.262	
Diarrhoea, n (%)	2 (13.3)	4 (14.3)	6 (10.7)	11 (9.7)	0.862
Odds Ratio (95% CIs) [1], P-Value		1.083 (0.174, 6.731), 0.932		0.899 (0.314, 2.570), 0.842	
Relative Risk (95% CIs) [2], P-Value		1.071 (0.221, 5.188), 0.932		0.909 (0.354, 2.330), 0.842	
Risk Difference (95% CIs) [2], P-Value		0.010 (-0.206, 0.225), 0.931		-0.010 (-0.108, 0.088), 0.844	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.2.1.1.5a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Infections and infestations, n (%)	1 (6.7)	4 (14.3)	7 (12.5)	13 (11.5)	0.458
Odds Ratio (95% CIs) [1], P-Value		2.333 (0.237, 23.002), 0.458		0.910 (0.341, 2.426), 0.850	
Relative Risk (95% CIs) [2], P-Value		2.143 (0.262, 17.493), 0.477		0.920 (0.389, 2.178), 0.850	
Risk Difference (95% CIs) [2], P-Value		0.076 (-0.105, 0.257), 0.409		-0.010 (-0.115, 0.095), 0.852	
COVID-19, n (%)	1 (6.7)	4 (14.3)	7 (12.5)	13 (11.5)	0.458
Odds Ratio (95% CIs) [1], P-Value		2.333 (0.237, 23.002), 0.458		0.910 (0.341, 2.426), 0.850	
Relative Risk (95% CIs) [2], P-Value		2.143 (0.262, 17.493), 0.477		0.920 (0.389, 2.178), 0.850	
Risk Difference (95% CIs) [2], P-Value		0.076 (-0.105, 0.257), 0.409		-0.010 (-0.115, 0.095), 0.852	
Nervous system disorders, n (%)	3 (20.0)	9 (32.1)	14 (25.0)	29 (25.7)	0.477
Odds Ratio (95% CIs) [1], P-Value		1.895 (0.426, 8.434), 0.398		1.036 (0.495, 2.166), 0.926	
Relative Risk (95% CIs) [2], P-Value		1.607 (0.511, 5.057), 0.417		1.027 (0.591, 1.782), 0.926	
Risk Difference (95% CIs) [2], P-Value		0.121 (-0.145, 0.388), 0.371		0.007 (-0.132, 0.146), 0.925	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.2.1.1.5a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Nervous system disorders (cont.)					
Headache, n (%)	3 (20.0)	7 (25.0)	11 (19.6)	20 (17.7)	0.638
Odds Ratio (95% CIs) [1], P-Value		1.333 (0.290, 6.140), 0.711		0.880 (0.389, 1.992), 0.759	
Relative Risk (95% CIs) [2], P-Value		1.250 (0.377, 4.143), 0.715		0.901 (0.465, 1.747), 0.758	
Risk Difference (95% CIs) [2], P-Value		0.050 (-0.208, 0.308), 0.704		-0.019 (-0.145, 0.106), 0.762	
Dizziness, n (%)	1 (6.7)	4 (14.3)	5 (8.9)	12 (10.6)	0.613
Odds Ratio (95% CIs) [1], P-Value		2.333 (0.237, 23.002), 0.458		1.212 (0.405, 3.627), 0.731	
Relative Risk (95% CIs) [2], P-Value		2.143 (0.262, 17.493), 0.477		1.189 (0.441, 3.210), 0.732	
Risk Difference (95% CIs) [2], P-Value		0.076 (-0.105, 0.257), 0.409		0.017 (-0.077, 0.111), 0.724	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.2.1.1.6a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	Number of Baseline BSC <4 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	Number of Baseline BSC >=4 Avapritinib 25 mg (N=69)	P-Value [3]
Gastrointestinal disorders, n (%)	9 (25.7)	15 (20.8)	7 (19.4)	12 (17.4)	0.848
Odds Ratio (95% CIs) [1], P-Value		0.760 (0.295, 1.961), 0.570		0.872 (0.310, 2.452), 0.795	
Relative Risk (95% CIs) [2], P-Value		0.810 (0.394, 1.666), 0.567		0.894 (0.386, 2.073), 0.795	
Risk Difference (95% CIs) [2], P-Value		-0.049 (-0.221, 0.124), 0.579		-0.021 (-0.178, 0.137), 0.798	
Nausea, n (%)	8 (22.9)	9 (12.5)	4 (11.1)	9 (13.0)	0.275
Odds Ratio (95% CIs) [1], P-Value		0.482 (0.168, 1.383), 0.169		1.200 (0.343, 4.203), 0.775	
Relative Risk (95% CIs) [2], P-Value		0.547 (0.231, 1.296), 0.170		1.174 (0.388, 3.550), 0.776	
Risk Difference (95% CIs) [2], P-Value		-0.104 (-0.262, 0.055), 0.201		0.019 (-0.110, 0.149), 0.770	
Diarrhoea, n (%)	3 (8.6)	7 (9.7)	5 (13.9)	8 (11.6)	0.715
Odds Ratio (95% CIs) [1], P-Value		1.149 (0.278, 4.739), 0.848		0.813 (0.245, 2.694), 0.735	
Relative Risk (95% CIs) [2], P-Value		1.134 (0.312, 4.124), 0.848		0.835 (0.294, 2.367), 0.734	
Risk Difference (95% CIs) [2], P-Value		0.012 (-0.104, 0.127), 0.845		-0.023 (-0.159, 0.113), 0.741	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.2.1.1.6a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Infections and infestations, n (%)	2 (5.7)	8 (11.1)	6 (16.7)	9 (13.0)	0.311
Odds Ratio (95% CIs) [1], P-Value		2.063 (0.414, 10.271), 0.368		0.750 (0.244, 2.304), 0.615	
Relative Risk (95% CIs) [2], P-Value		1.944 (0.436, 8.679), 0.384		0.783 (0.302, 2.026), 0.613	
Risk Difference (95% CIs) [2], P-Value		0.054 (-0.052, 0.160), 0.317		-0.036 (-0.182, 0.109), 0.625	
COVID-19, n (%)	2 (5.7)	8 (11.1)	6 (16.7)	9 (13.0)	0.311
Odds Ratio (95% CIs) [1], P-Value		2.063 (0.414, 10.271), 0.368		0.750 (0.244, 2.304), 0.615	
Relative Risk (95% CIs) [2], P-Value		1.944 (0.436, 8.679), 0.384		0.783 (0.302, 2.026), 0.613	
Risk Difference (95% CIs) [2], P-Value		0.054 (-0.052, 0.160), 0.317		-0.036 (-0.182, 0.109), 0.625	
Nervous system disorders, n (%)	11 (31.4)	18 (25.0)	6 (16.7)	20 (29.0)	0.135
Odds Ratio (95% CIs) [1], P-Value		0.727 (0.298, 1.773), 0.483		2.041 (0.736, 5.655), 0.165	
Relative Risk (95% CIs) [2], P-Value		0.795 (0.423, 1.497), 0.478		1.739 (0.767, 3.943), 0.185	
Risk Difference (95% CIs) [2], P-Value		-0.064 (-0.248, 0.119), 0.492		0.123 (-0.039, 0.285), 0.136	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.2.1.1.6a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Nervous system disorders (cont.)					
Headache, n (%)	9 (25.7)	15 (20.8)	5 (13.9)	12 (17.4)	0.473
Odds Ratio (95% CIs) [1], P-Value		0.760 (0.295, 1.961), 0.570		1.305 (0.421, 4.046), 0.644	
Relative Risk (95% CIs) [2], P-Value		0.810 (0.394, 1.666), 0.567		1.252 (0.478, 3.278), 0.647	
Risk Difference (95% CIs) [2], P-Value		-0.049 (-0.221, 0.124), 0.579		0.035 (-0.109, 0.179), 0.634	
Dizziness, n (%)	4 (11.4)	5 (6.9)	2 (5.6)	11 (15.9)	0.107
Odds Ratio (95% CIs) [1], P-Value		0.578 (0.145, 2.304), 0.433		3.224 (0.674, 15.420), 0.125	
Relative Risk (95% CIs) [2], P-Value		0.608 (0.174, 2.123), 0.435		2.870 (0.672, 12.255), 0.155	
Risk Difference (95% CIs) [2], P-Value		-0.045 (-0.165, 0.076), 0.466		0.104 (-0.010, 0.218), 0.075	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.2.1.1.7a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Gastrointestinal disorders, n (%)	1 (14.3)	2 (10.5)	15 (23.4)	25 (20.5)	0.897
Odds Ratio (95% CIs) [1], P-Value		0.706 (0.054, 9.265), 0.790		0.842 (0.407, 1.741), 0.642	
Relative Risk (95% CIs) [2], P-Value		0.737 (0.079, 6.912), 0.789		0.874 (0.497, 1.537), 0.641	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.331, 0.256), 0.802		-0.029 (-0.156, 0.097), 0.647	
Nausea, n (%)	0	1 (5.3)	12 (18.8)	17 (13.9)	0.951
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.536		0.702 (0.312, 1.578), 0.390	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.743 (0.379, 1.458), 0.388	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		-0.048 (-0.162, 0.066), 0.406	
Diarrhoea, n (%)	1 (14.3)	2 (10.5)	7 (10.9)	13 (10.7)	0.820
Odds Ratio (95% CIs) [1], P-Value		0.706 (0.054, 9.265), 0.790		0.971 (0.367, 2.570), 0.953	
Relative Risk (95% CIs) [2], P-Value		0.737 (0.079, 6.912), 0.789		0.974 (0.409, 2.320), 0.953	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.331, 0.256), 0.802		-0.003 (-0.097, 0.091), 0.953	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.2.1.1.7a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Infections and infestations, n (%)	1 (14.3)	1 (5.3)	7 (10.9)	16 (13.1)	0.405
Odds Ratio (95% CIs) [1], P-Value		0.333 (0.018, 6.191), 0.444		1.229 (0.478, 3.161), 0.668	
Relative Risk (95% CIs) [2], P-Value		0.368 (0.026, 5.126), 0.457		1.199 (0.520, 2.764), 0.670	
Risk Difference (95% CIs) [2], P-Value		-0.090 (-0.368, 0.188), 0.525		0.022 (-0.075, 0.119), 0.660	
COVID-19, n (%)	1 (14.3)	1 (5.3)	7 (10.9)	16 (13.1)	0.405
Odds Ratio (95% CIs) [1], P-Value		0.333 (0.018, 6.191), 0.444		1.229 (0.478, 3.161), 0.668	
Relative Risk (95% CIs) [2], P-Value		0.368 (0.026, 5.126), 0.457		1.199 (0.520, 2.764), 0.670	
Risk Difference (95% CIs) [2], P-Value		-0.090 (-0.368, 0.188), 0.525		0.022 (-0.075, 0.119), 0.660	
Nervous system disorders, n (%)	1 (14.3)	2 (10.5)	16 (25.0)	36 (29.5)	0.672
Odds Ratio (95% CIs) [1], P-Value		0.706 (0.054, 9.265), 0.790		1.256 (0.632, 2.495), 0.515	
Relative Risk (95% CIs) [2], P-Value		0.737 (0.079, 6.912), 0.789		1.180 (0.712, 1.956), 0.520	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.331, 0.256), 0.802		0.045 (-0.088, 0.179), 0.508	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.2.1.1.7a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Nervous system disorders (cont.)					
Headache, n (%)	1 (14.3)	1 (5.3)	13 (20.3)	26 (21.3)	0.451
Odds Ratio (95% CIs) [1], P-Value		0.333 (0.018, 6.191), 0.444		1.063 (0.503, 2.243), 0.874	
Relative Risk (95% CIs) [2], P-Value		0.368 (0.026, 5.126), 0.457		1.049 (0.580, 1.899), 0.874	
Risk Difference (95% CIs) [2], P-Value		-0.090 (-0.368, 0.188), 0.525		0.010 (-0.112, 0.132), 0.873	
Dizziness, n (%)	0	1 (5.3)	6 (9.4)	15 (12.3)	0.959
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.536		1.355 (0.499, 3.681), 0.550	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.311 (0.535, 3.216), 0.554	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		0.029 (-0.063, 0.121), 0.535	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.2.1.1.8a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes		No		P-Value [3]
	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	
Gastrointestinal disorders, n (%)	1 (9.1)	6 (23.1)	15 (25.0)	21 (18.3)	0.215
Odds Ratio (95% CIs) [1], P-Value		3.000 (0.317, 28.434), 0.321		0.670 (0.316, 1.421), 0.295	
Relative Risk (95% CIs) [2], P-Value		2.538 (0.345, 18.685), 0.360		0.730 (0.407, 1.310), 0.292	
Risk Difference (95% CIs) [2], P-Value		0.140 (-0.095, 0.375), 0.243		-0.067 (-0.198, 0.063), 0.311	
Nausea, n (%)	1 (9.1)	5 (19.2)	11 (18.3)	13 (11.3)	0.249
Odds Ratio (95% CIs) [1], P-Value		2.381 (0.245, 23.168), 0.444		0.568 (0.237, 1.358), 0.199	
Relative Risk (95% CIs) [2], P-Value		2.115 (0.278, 16.075), 0.469		0.617 (0.294, 1.292), 0.200	
Risk Difference (95% CIs) [2], P-Value		0.101 (-0.126, 0.329), 0.383		-0.070 (-0.184, 0.043), 0.226	
Diarrhoea, n (%)	0	4 (15.4)	8 (13.3)	11 (9.6)	0.959
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.168		0.688 (0.261, 1.813), 0.447	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.717 (0.305, 1.688), 0.447	
Risk Difference (95% CIs) [2], P-Value		0.154 (0.015, 0.293), 0.030		-0.038 (-0.139, 0.064), 0.467	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.2.1.1.8a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
Infections and infestations, n (%)	1 (9.1)	5 (19.2)	7 (11.7)	12 (10.4)	0.433
Odds Ratio (95% CIs) [1], P-Value		2.381 (0.245, 23.168), 0.444		0.882 (0.328, 2.372), 0.804	
Relative Risk (95% CIs) [2], P-Value		2.115 (0.278, 16.075), 0.469		0.894 (0.372, 2.153), 0.803	
Risk Difference (95% CIs) [2], P-Value		0.101 (-0.126, 0.329), 0.383		-0.012 (-0.111, 0.086), 0.807	
COVID-19, n (%)	1 (9.1)	5 (19.2)	7 (11.7)	12 (10.4)	0.433
Odds Ratio (95% CIs) [1], P-Value		2.381 (0.245, 23.168), 0.444		0.882 (0.328, 2.372), 0.804	
Relative Risk (95% CIs) [2], P-Value		2.115 (0.278, 16.075), 0.469		0.894 (0.372, 2.153), 0.803	
Risk Difference (95% CIs) [2], P-Value		0.101 (-0.126, 0.329), 0.383		-0.012 (-0.111, 0.086), 0.807	
Nervous system disorders, n (%)	1 (9.1)	6 (23.1)	16 (26.7)	32 (27.8)	0.387
Odds Ratio (95% CIs) [1], P-Value		3.000 (0.317, 28.434), 0.321		1.060 (0.525, 2.141), 0.870	
Relative Risk (95% CIs) [2], P-Value		2.538 (0.345, 18.685), 0.360		1.043 (0.625, 1.742), 0.871	
Risk Difference (95% CIs) [2], P-Value		0.140 (-0.095, 0.375), 0.243		0.012 (-0.127, 0.150), 0.870	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.2.1.1.8a
Summary of Adverse Events Occurred >= 10 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
Nervous system disorders (cont.)					
Headache, n (%)	0	3 (11.5)	14 (23.3)	24 (20.9)	0.952
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.240		0.867 (0.410, 1.832), 0.707	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.894 (0.501, 1.598), 0.706	
Risk Difference (95% CIs) [2], P-Value		0.115 (-0.007, 0.238), 0.066		-0.025 (-0.155, 0.106), 0.711	
Dizziness, n (%)	1 (9.1)	3 (11.5)	5 (8.3)	13 (11.3)	0.957
Odds Ratio (95% CIs) [1], P-Value		1.304 (0.120, 14.119), 0.827		1.402 (0.475, 4.138), 0.539	
Relative Risk (95% CIs) [2], P-Value		1.269 (0.148, 10.902), 0.828		1.357 (0.508, 3.625), 0.543	
Risk Difference (95% CIs) [2], P-Value		0.024 (-0.185, 0.234), 0.819		0.030 (-0.061, 0.120), 0.521	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge10p-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.2.1.1.1.1.1a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Gastrointestinal disorders, n (%)	13 (21.7)	26 (19.7)	3 (27.3)	1 (11.1)	0.457
Odds Ratio (95% CIs) [1], P-Value		0.887 (0.419, 1.876), 0.753		0.333 (0.028, 3.926), 0.369	
Relative Risk (95% CIs) [2], P-Value		0.909 (0.503, 1.643), 0.752		0.407 (0.051, 3.276), 0.399	
Risk Difference (95% CIs) [2], P-Value		-0.020 (-0.144, 0.105), 0.756		-0.162 (-0.495, 0.172), 0.343	
Nausea, n (%)	9 (15.0)	17 (12.9)	3 (27.3)	1 (11.1)	0.490
Odds Ratio (95% CIs) [1], P-Value		0.838 (0.350, 2.005), 0.691		0.333 (0.028, 3.926), 0.369	
Relative Risk (95% CIs) [2], P-Value		0.859 (0.406, 1.814), 0.690		0.407 (0.051, 3.276), 0.399	
Risk Difference (95% CIs) [2], P-Value		-0.021 (-0.128, 0.086), 0.697		-0.162 (-0.495, 0.172), 0.343	
Diarrhoea, n (%)	6 (10.0)	15 (11.4)	2 (18.2)	0	0.944
Odds Ratio (95% CIs) [1], P-Value		1.154 (0.424, 3.137), 0.779		NE (NE, NE), 0.178	
Relative Risk (95% CIs) [2], P-Value		1.136 (0.464, 2.784), 0.780		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.014 (-0.080, 0.107), 0.774		-0.182 (-0.410, 0.046), 0.118	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.1a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
General disorders and administration site conditions, n (%)	9 (15.0)	26 (19.7)	1 (9.1)	3 (33.3)	0.337
Odds Ratio (95% CIs) [1], P-Value		1.390 (0.607, 3.182), 0.435		5.000 (0.419, 59.657), 0.178	
Relative Risk (95% CIs) [2], P-Value		1.313 (0.656, 2.628), 0.442		3.667 (0.456, 29.487), 0.222	
Risk Difference (95% CIs) [2], P-Value		0.047 (-0.066, 0.160), 0.415		0.242 (-0.109, 0.594), 0.177	
Fatigue, n (%)	5 (8.3)	14 (10.6)	1 (9.1)	0	0.950
Odds Ratio (95% CIs) [1], P-Value		1.305 (0.448, 3.805), 0.625		NE (NE, NE), 0.353	
Relative Risk (95% CIs) [2], P-Value		1.273 (0.480, 3.372), 0.628		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.023 (-0.065, 0.110), 0.611		-0.091 (-0.261, 0.079), 0.294	
Oedema peripheral, n (%)	3 (5.0)	10 (7.6)	0	2 (22.2)	0.949
Odds Ratio (95% CIs) [1], P-Value		1.557 (0.413, 5.877), 0.510		NE (NE, NE), 0.099	
Relative Risk (95% CIs) [2], P-Value		1.515 (0.433, 5.307), 0.516		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.026 (-0.046, 0.097), 0.479		0.222 (-0.049, 0.494), 0.109	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.1a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
General disorders and administration site conditions (cont.)					
Face oedema, n (%)	1 (1.7)	8 (6.1)	0	2 (22.2)	0.955
Odds Ratio (95% CIs) [1], P-Value		3.806 (0.465, 31.141), 0.182		NE (NE, NE), 0.099	
Relative Risk (95% CIs) [2], P-Value		3.636 (0.465, 28.426), 0.219		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.044 (-0.008, 0.096), 0.098		0.222 (-0.049, 0.494), 0.109	
Infections and infestations, n (%)	7 (11.7)	16 (12.1)	1 (9.1)	1 (11.1)	0.909
Odds Ratio (95% CIs) [1], P-Value		1.044 (0.406, 2.689), 0.928		1.250 (0.067, 23.259), 0.881	
Relative Risk (95% CIs) [2], P-Value		1.039 (0.451, 2.392), 0.928		1.222 (0.088, 16.924), 0.881	
Risk Difference (95% CIs) [2], P-Value		0.005 (-0.094, 0.103), 0.928		0.020 (-0.246, 0.287), 0.882	
COVID-19, n (%)	7 (11.7)	16 (12.1)	1 (9.1)	1 (11.1)	0.909
Odds Ratio (95% CIs) [1], P-Value		1.044 (0.406, 2.689), 0.928		1.250 (0.067, 23.259), 0.881	
Relative Risk (95% CIs) [2], P-Value		1.039 (0.451, 2.392), 0.928		1.222 (0.088, 16.924), 0.881	
Risk Difference (95% CIs) [2], P-Value		0.005 (-0.094, 0.103), 0.928		0.020 (-0.246, 0.287), 0.882	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.1a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Musculoskeletal and connective tissue disorders, n (%)	4 (6.7)	10 (7.6)	1 (9.1)	1 (11.1)	0.958
Odds Ratio (95% CIs) [1], P-Value		1.148 (0.345, 3.817), 0.822		1.250 (0.067, 23.259), 0.881	
Relative Risk (95% CIs) [2], P-Value		1.136 (0.371, 3.478), 0.823		1.222 (0.088, 16.924), 0.881	
Risk Difference (95% CIs) [2], P-Value		0.009 (-0.069, 0.087), 0.818		0.020 (-0.246, 0.287), 0.882	
Arthralgia, n (%)	4 (6.7)	10 (7.6)	1 (9.1)	1 (11.1)	0.958
Odds Ratio (95% CIs) [1], P-Value		1.148 (0.345, 3.817), 0.822		1.250 (0.067, 23.259), 0.881	
Relative Risk (95% CIs) [2], P-Value		1.136 (0.371, 3.478), 0.823		1.222 (0.088, 16.924), 0.881	
Risk Difference (95% CIs) [2], P-Value		0.009 (-0.069, 0.087), 0.818		0.020 (-0.246, 0.287), 0.882	
Nervous system disorders, n (%)	13 (21.7)	37 (28.0)	4 (36.4)	1 (11.1)	0.148
Odds Ratio (95% CIs) [1], P-Value		1.408 (0.684, 2.899), 0.352		0.219 (0.020, 2.447), 0.194	
Relative Risk (95% CIs) [2], P-Value		1.294 (0.744, 2.250), 0.362		0.306 (0.041, 2.272), 0.247	
Risk Difference (95% CIs) [2], P-Value		0.064 (-0.066, 0.193), 0.335		-0.253 (-0.603, 0.098), 0.158	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.1a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Nervous system disorders (cont.)					
Headache, n (%)	11 (18.3)	26 (19.7)	3 (27.3)	1 (11.1)	0.368
Odds Ratio (95% CIs) [1], P-Value		1.093 (0.500, 2.388), 0.824		0.333 (0.028, 3.926), 0.369	
Relative Risk (95% CIs) [2], P-Value		1.074 (0.569, 2.028), 0.825		0.407 (0.051, 3.276), 0.399	
Risk Difference (95% CIs) [2], P-Value		0.014 (-0.105, 0.133), 0.822		-0.162 (-0.495, 0.172), 0.343	
Dizziness, n (%)	5 (8.3)	16 (12.1)	1 (9.1)	0	0.948
Odds Ratio (95% CIs) [1], P-Value		1.517 (0.529, 4.354), 0.436		NE (NE, NE), 0.353	
Relative Risk (95% CIs) [2], P-Value		1.455 (0.559, 3.786), 0.443		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.052, 0.127), 0.406		-0.091 (-0.261, 0.079), 0.294	
Skin and subcutaneous tissue disorders, n (%)	4 (6.7)	11 (8.3)	1 (9.1)	0	0.954
Odds Ratio (95% CIs) [1], P-Value		1.273 (0.388, 4.173), 0.690		NE (NE, NE), 0.353	
Relative Risk (95% CIs) [2], P-Value		1.250 (0.415, 3.766), 0.692		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.017 (-0.062, 0.095), 0.678		-0.091 (-0.261, 0.079), 0.294	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.1a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Skin and subcutaneous tissue disorders (cont.)					
Pruritus, n (%)	4 (6.7)	11 (8.3)	1 (9.1)	0	0.954
Odds Ratio (95% CIs) [1], P-Value		1.273 (0.388, 4.173), 0.690		NE (NE, NE), 0.353	
Relative Risk (95% CIs) [2], P-Value		1.250 (0.415, 3.766), 0.692		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.017 (-0.062, 0.095), 0.678		-0.091 (-0.261, 0.079), 0.294	
Vascular disorders, n (%)	3 (5.0)	13 (9.8)	0	0	0.996
Odds Ratio (95% CIs) [1], P-Value		2.076 (0.569, 7.574), 0.260		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		1.970 (0.583, 6.657), 0.275		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.048 (-0.027, 0.123), 0.205		NA (NA, NA), NA	
Flushing, n (%)	3 (5.0)	13 (9.8)	0	0	0.996
Odds Ratio (95% CIs) [1], P-Value		2.076 (0.569, 7.574), 0.260		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		1.970 (0.583, 6.657), 0.275		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.048 (-0.027, 0.123), 0.205		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.2a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Gastrointestinal disorders, n (%)	4 (23.5)	9 (22.0)	12 (22.2)	18 (18.0)	0.829
Odds Ratio (95% CIs) [1], P-Value		0.914 (0.239, 3.500), 0.896		0.768 (0.338, 1.744), 0.528	
Relative Risk (95% CIs) [2], P-Value		0.933 (0.332, 2.622), 0.895		0.810 (0.422, 1.553), 0.526	
Risk Difference (95% CIs) [2], P-Value		-0.016 (-0.254, 0.222), 0.897		-0.042 (-0.176, 0.092), 0.537	
Nausea, n (%)	4 (23.5)	7 (17.1)	8 (14.8)	11 (11.0)	0.944
Odds Ratio (95% CIs) [1], P-Value		0.669 (0.168, 2.672), 0.568		0.711 (0.267, 1.889), 0.492	
Relative Risk (95% CIs) [2], P-Value		0.726 (0.244, 2.160), 0.564		0.743 (0.318, 1.734), 0.492	
Risk Difference (95% CIs) [2], P-Value		-0.065 (-0.297, 0.168), 0.586		-0.038 (-0.151, 0.075), 0.508	
Diarrhoea, n (%)	1 (5.9)	3 (7.3)	7 (13.0)	12 (12.0)	0.804
Odds Ratio (95% CIs) [1], P-Value		1.263 (0.122, 13.078), 0.844		0.916 (0.338, 2.482), 0.862	
Relative Risk (95% CIs) [2], P-Value		1.244 (0.139, 11.130), 0.845		0.926 (0.387, 2.213), 0.862	
Risk Difference (95% CIs) [2], P-Value		0.014 (-0.123, 0.152), 0.838		-0.010 (-0.120, 0.100), 0.864	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.2a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
General disorders and administration site conditions, n (%)	5 (29.4)	8 (19.5)	5 (9.3)	21 (21.0)	0.077
Odds Ratio (95% CIs) [1], P-Value		0.582 (0.159, 2.131), 0.411		2.605 (0.922, 7.358), 0.063	
Relative Risk (95% CIs) [2], P-Value		0.663 (0.253, 1.739), 0.404		2.268 (0.906, 5.676), 0.080	
Risk Difference (95% CIs) [2], P-Value		-0.099 (-0.347, 0.149), 0.434		0.117 (0.006, 0.229), 0.038	
Fatigue, n (%)	4 (23.5)	4 (9.8)	2 (3.7)	10 (10.0)	0.058
Odds Ratio (95% CIs) [1], P-Value		0.351 (0.077, 1.612), 0.166		2.889 (0.609, 13.694), 0.164	
Relative Risk (95% CIs) [2], P-Value		0.415 (0.117, 1.470), 0.173		2.700 (0.614, 11.881), 0.189	
Risk Difference (95% CIs) [2], P-Value		-0.138 (-0.359, 0.083), 0.222		0.063 (-0.014, 0.140), 0.111	
Oedema peripheral, n (%)	1 (5.9)	4 (9.8)	2 (3.7)	8 (8.0)	0.850
Odds Ratio (95% CIs) [1], P-Value		1.730 (0.179, 16.716), 0.632		2.261 (0.463, 11.046), 0.302	
Relative Risk (95% CIs) [2], P-Value		1.659 (0.200, 13.778), 0.640		2.160 (0.475, 9.814), 0.319	
Risk Difference (95% CIs) [2], P-Value		0.039 (-0.105, 0.183), 0.598		0.043 (-0.030, 0.116), 0.250	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.2a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
General disorders and administration site conditions (cont.)					
Face oedema, n (%)	0	2 (4.9)	1 (1.9)	8 (8.0)	0.958
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.354		4.609 (0.561, 37.868), 0.121	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		4.320 (0.555, 33.636), 0.162	
Risk Difference (95% CIs) [2], P-Value		0.049 (-0.017, 0.115), 0.147		0.061 (-0.003, 0.126), 0.060	
Infections and infestations, n (%)	4 (23.5)	5 (12.2)	4 (7.4)	12 (12.0)	0.166
Odds Ratio (95% CIs) [1], P-Value		0.451 (0.105, 1.943), 0.278		1.705 (0.522, 5.567), 0.373	
Relative Risk (95% CIs) [2], P-Value		0.518 (0.158, 1.699), 0.278		1.620 (0.549, 4.780), 0.382	
Risk Difference (95% CIs) [2], P-Value		-0.113 (-0.338, 0.112), 0.324		0.046 (-0.049, 0.140), 0.341	
COVID-19, n (%)	4 (23.5)	5 (12.2)	4 (7.4)	12 (12.0)	0.166
Odds Ratio (95% CIs) [1], P-Value		0.451 (0.105, 1.943), 0.278		1.705 (0.522, 5.567), 0.373	
Relative Risk (95% CIs) [2], P-Value		0.518 (0.158, 1.699), 0.278		1.620 (0.549, 4.780), 0.382	
Risk Difference (95% CIs) [2], P-Value		-0.113 (-0.338, 0.112), 0.324		0.046 (-0.049, 0.140), 0.341	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.2a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Musculoskeletal and connective tissue disorders, n (%)	1 (5.9)	2 (4.9)	4 (7.4)	9 (9.0)	0.771
Odds Ratio (95% CIs) [1], P-Value		0.821 (0.069, 9.700), 0.875		1.236 (0.362, 4.218), 0.734	
Relative Risk (95% CIs) [2], P-Value		0.829 (0.080, 8.548), 0.875		1.215 (0.392, 3.762), 0.736	
Risk Difference (95% CIs) [2], P-Value		-0.010 (-0.140, 0.120), 0.879		0.016 (-0.074, 0.106), 0.728	
Arthralgia, n (%)	1 (5.9)	2 (4.9)	4 (7.4)	9 (9.0)	0.771
Odds Ratio (95% CIs) [1], P-Value		0.821 (0.069, 9.700), 0.875		1.236 (0.362, 4.218), 0.734	
Relative Risk (95% CIs) [2], P-Value		0.829 (0.080, 8.548), 0.875		1.215 (0.392, 3.762), 0.736	
Risk Difference (95% CIs) [2], P-Value		-0.010 (-0.140, 0.120), 0.879		0.016 (-0.074, 0.106), 0.728	
Nervous system disorders, n (%)	0	10 (24.4)	17 (31.5)	28 (28.0)	0.953
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.025		0.846 (0.411, 1.741), 0.650	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.889 (0.538, 1.472), 0.648	
Risk Difference (95% CIs) [2], P-Value		0.244 (0.112, 0.375), <0.001		-0.035 (-0.187, 0.117), 0.653	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.2a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Nervous system disorders (cont.)					
Headache, n (%)	0	9 (22.0)	14 (25.9)	18 (18.0)	0.934
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.036		0.627 (0.283, 1.388), 0.247	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.694 (0.375, 1.284), 0.245	
Risk Difference (95% CIs) [2], P-Value		0.220 (0.093, 0.346), <0.001		-0.079 (-0.218, 0.060), 0.264	
Dizziness, n (%)	0	4 (9.8)	6 (11.1)	12 (12.0)	0.954
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.182		1.091 (0.385, 3.090), 0.870	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.080 (0.429, 2.717), 0.870	
Risk Difference (95% CIs) [2], P-Value		0.098 (0.007, 0.188), 0.035		0.009 (-0.096, 0.114), 0.869	
Skin and subcutaneous tissue disorders, n (%)	0	4 (9.8)	5 (9.3)	7 (7.0)	0.958
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.182		0.738 (0.222, 2.446), 0.618	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.756 (0.252, 2.269), 0.618	
Risk Difference (95% CIs) [2], P-Value		0.098 (0.007, 0.188), 0.035		-0.023 (-0.115, 0.069), 0.631	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.2a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Skin and subcutaneous tissue disorders (cont.)					
Pruritus, n (%)	0	4 (9.8)	5 (9.3)	7 (7.0)	0.958
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.182		0.738 (0.222, 2.446), 0.618	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.756 (0.252, 2.269), 0.618	
Risk Difference (95% CIs) [2], P-Value		0.098 (0.007, 0.188), 0.035		-0.023 (-0.115, 0.069), 0.631	
Vascular disorders, n (%)	1 (5.9)	4 (9.8)	2 (3.7)	9 (9.0)	0.778
Odds Ratio (95% CIs) [1], P-Value		1.730 (0.179, 16.716), 0.632		2.571 (0.535, 12.355), 0.223	
Relative Risk (95% CIs) [2], P-Value		1.659 (0.200, 13.778), 0.640		2.430 (0.544, 10.847), 0.245	
Risk Difference (95% CIs) [2], P-Value		0.039 (-0.105, 0.183), 0.598		0.053 (-0.022, 0.128), 0.169	
Flushing, n (%)	1 (5.9)	4 (9.8)	2 (3.7)	9 (9.0)	0.778
Odds Ratio (95% CIs) [1], P-Value		1.730 (0.179, 16.716), 0.632		2.571 (0.535, 12.355), 0.223	
Relative Risk (95% CIs) [2], P-Value		1.659 (0.200, 13.778), 0.640		2.430 (0.544, 10.847), 0.245	
Risk Difference (95% CIs) [2], P-Value		0.039 (-0.105, 0.183), 0.598		0.053 (-0.022, 0.128), 0.169	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.3a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Gastrointestinal disorders, n (%)	7 (21.2)	9 (15.0)	9 (23.7)	18 (22.2)	0.640
Odds Ratio (95% CIs) [1], P-Value		0.655 (0.219, 1.959), 0.448		0.921 (0.369, 2.294), 0.859	
Relative Risk (95% CIs) [2], P-Value		0.707 (0.290, 1.725), 0.446		0.938 (0.465, 1.892), 0.859	
Risk Difference (95% CIs) [2], P-Value		-0.062 (-0.228, 0.104), 0.464		-0.015 (-0.177, 0.148), 0.860	
Nausea, n (%)	5 (15.2)	7 (11.7)	7 (18.4)	11 (13.6)	0.941
Odds Ratio (95% CIs) [1], P-Value		0.740 (0.215, 2.545), 0.631		0.696 (0.247, 1.964), 0.492	
Relative Risk (95% CIs) [2], P-Value		0.770 (0.265, 2.236), 0.631		0.737 (0.310, 1.752), 0.490	
Risk Difference (95% CIs) [2], P-Value		-0.035 (-0.182, 0.112), 0.642		-0.048 (-0.192, 0.096), 0.510	
Diarrhoea, n (%)	4 (12.1)	5 (8.3)	4 (10.5)	10 (12.3)	0.528
Odds Ratio (95% CIs) [1], P-Value		0.659 (0.164, 2.645), 0.554		1.197 (0.350, 4.094), 0.774	
Relative Risk (95% CIs) [2], P-Value		0.687 (0.198, 2.386), 0.555		1.173 (0.393, 3.501), 0.775	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.169, 0.094), 0.572		0.018 (-0.103, 0.139), 0.768	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.3a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
General disorders and administration site conditions, n (%)	4 (12.1)	14 (23.3)	6 (15.8)	15 (18.5)	0.460
Odds Ratio (95% CIs) [1], P-Value		2.207 (0.662, 7.359), 0.190		1.212 (0.430, 3.418), 0.716	
Relative Risk (95% CIs) [2], P-Value		1.925 (0.689, 5.375), 0.211		1.173 (0.494, 2.785), 0.718	
Risk Difference (95% CIs) [2], P-Value		0.112 (-0.042, 0.267), 0.155		0.027 (-0.116, 0.171), 0.709	
Fatigue, n (%)	1 (3.0)	8 (13.3)	5 (13.2)	6 (7.4)	0.076
Odds Ratio (95% CIs) [1], P-Value		4.923 (0.588, 41.220), 0.108		0.528 (0.150, 1.853), 0.313	
Relative Risk (95% CIs) [2], P-Value		4.400 (0.575, 33.670), 0.154		0.563 (0.183, 1.730), 0.316	
Risk Difference (95% CIs) [2], P-Value		0.103 (-0.001, 0.207), 0.052		-0.058 (-0.179, 0.064), 0.354	
Oedema peripheral, n (%)	2 (6.1)	6 (10.0)	1 (2.6)	6 (7.4)	0.696
Odds Ratio (95% CIs) [1], P-Value		1.722 (0.327, 9.059), 0.517		2.960 (0.344, 25.495), 0.302	
Relative Risk (95% CIs) [2], P-Value		1.650 (0.353, 7.719), 0.525		2.815 (0.351, 22.568), 0.330	
Risk Difference (95% CIs) [2], P-Value		0.039 (-0.072, 0.151), 0.488		0.048 (-0.029, 0.124), 0.221	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.3a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
General disorders and administration site conditions (cont.)					
Face oedema, n (%)	1 (3.0)	5 (8.3)	0	5 (6.2)	0.954
Odds Ratio (95% CIs) [1], P-Value		2.909 (0.325, 26.014), 0.319		NE (NE, NE), 0.118	
Relative Risk (95% CIs) [2], P-Value		2.750 (0.335, 22.560), 0.346		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.038, 0.144), 0.254		0.062 (0.009, 0.114), 0.021	
Infections and infestations, n (%)	3 (9.1)	4 (6.7)	5 (13.2)	13 (16.0)	0.561
Odds Ratio (95% CIs) [1], P-Value		0.714 (0.150, 3.403), 0.672		1.262 (0.415, 3.837), 0.681	
Relative Risk (95% CIs) [2], P-Value		0.733 (0.175, 3.081), 0.672		1.220 (0.469, 3.175), 0.684	
Risk Difference (95% CIs) [2], P-Value		-0.024 (-0.141, 0.092), 0.684		0.029 (-0.105, 0.163), 0.672	
COVID-19, n (%)	3 (9.1)	4 (6.7)	5 (13.2)	13 (16.0)	0.561
Odds Ratio (95% CIs) [1], P-Value		0.714 (0.150, 3.403), 0.672		1.262 (0.415, 3.837), 0.681	
Relative Risk (95% CIs) [2], P-Value		0.733 (0.175, 3.081), 0.672		1.220 (0.469, 3.175), 0.684	
Risk Difference (95% CIs) [2], P-Value		-0.024 (-0.141, 0.092), 0.684		0.029 (-0.105, 0.163), 0.672	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.3a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Musculoskeletal and connective tissue disorders, n (%)	3 (9.1)	2 (3.3)	2 (5.3)	9 (11.1)	0.130
Odds Ratio (95% CIs) [1], P-Value		0.345 (0.055, 2.177), 0.239		2.250 (0.462, 10.962), 0.304	
Relative Risk (95% CIs) [2], P-Value		0.367 (0.064, 2.085), 0.258		2.111 (0.479, 9.301), 0.323	
Risk Difference (95% CIs) [2], P-Value		-0.058 (-0.166, 0.051), 0.296		0.058 (-0.040, 0.157), 0.245	
Arthralgia, n (%)	3 (9.1)	2 (3.3)	2 (5.3)	9 (11.1)	0.130
Odds Ratio (95% CIs) [1], P-Value		0.345 (0.055, 2.177), 0.239		2.250 (0.462, 10.962), 0.304	
Relative Risk (95% CIs) [2], P-Value		0.367 (0.064, 2.085), 0.258		2.111 (0.479, 9.301), 0.323	
Risk Difference (95% CIs) [2], P-Value		-0.058 (-0.166, 0.051), 0.296		0.058 (-0.040, 0.157), 0.245	
Nervous system disorders, n (%)	7 (21.2)	18 (30.0)	10 (26.3)	20 (24.7)	0.419
Odds Ratio (95% CIs) [1], P-Value		1.592 (0.585, 4.330), 0.360		0.918 (0.380, 2.216), 0.849	
Relative Risk (95% CIs) [2], P-Value		1.414 (0.660, 3.032), 0.373		0.938 (0.488, 1.804), 0.849	
Risk Difference (95% CIs) [2], P-Value		0.088 (-0.094, 0.269), 0.342		-0.016 (-0.185, 0.152), 0.850	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.3a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Nervous system disorders (cont.)					
Headache, n (%)	7 (21.2)	14 (23.3)	7 (18.4)	13 (16.0)	0.694
Odds Ratio (95% CIs) [1], P-Value		1.130 (0.405, 3.156), 0.815		0.847 (0.308, 2.330), 0.747	
Relative Risk (95% CIs) [2], P-Value		1.100 (0.493, 2.452), 0.816		0.871 (0.378, 2.006), 0.746	
Risk Difference (95% CIs) [2], P-Value		0.021 (-0.155, 0.197), 0.813		-0.024 (-0.171, 0.123), 0.752	
Dizziness, n (%)	1 (3.0)	6 (10.0)	5 (13.2)	10 (12.3)	0.283
Odds Ratio (95% CIs) [1], P-Value		3.556 (0.409, 30.883), 0.223		0.930 (0.294, 2.936), 0.901	
Relative Risk (95% CIs) [2], P-Value		3.300 (0.415, 26.255), 0.259		0.938 (0.344, 2.555), 0.901	
Risk Difference (95% CIs) [2], P-Value		0.070 (-0.026, 0.166), 0.154		-0.008 (-0.137, 0.121), 0.902	
Skin and subcutaneous tissue disorders, n (%)	1 (3.0)	6 (10.0)	4 (10.5)	5 (6.2)	0.157
Odds Ratio (95% CIs) [1], P-Value		3.556 (0.409, 30.883), 0.223		0.559 (0.141, 2.213), 0.402	
Relative Risk (95% CIs) [2], P-Value		3.300 (0.415, 26.255), 0.259		0.586 (0.167, 2.061), 0.405	
Risk Difference (95% CIs) [2], P-Value		0.070 (-0.026, 0.166), 0.154		-0.044 (-0.154, 0.067), 0.441	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.3a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Skin and subcutaneous tissue disorders (cont.)					
Pruritus, n (%)	1 (3.0)	6 (10.0)	4 (10.5)	5 (6.2)	0.157
Odds Ratio (95% CIs) [1], P-Value		3.556 (0.409, 30.883), 0.223		0.559 (0.141, 2.213), 0.402	
Relative Risk (95% CIs) [2], P-Value		3.300 (0.415, 26.255), 0.259		0.586 (0.167, 2.061), 0.405	
Risk Difference (95% CIs) [2], P-Value		0.070 (-0.026, 0.166), 0.154		-0.044 (-0.154, 0.067), 0.441	
Vascular disorders, n (%)	2 (6.1)	2 (3.3)	1 (2.6)	11 (13.6)	0.106
Odds Ratio (95% CIs) [1], P-Value		0.534 (0.072, 3.981), 0.535		5.814 (0.722, 46.798), 0.064	
Relative Risk (95% CIs) [2], P-Value		0.550 (0.081, 3.727), 0.540		5.160 (0.691, 38.534), 0.110	
Risk Difference (95% CIs) [2], P-Value		-0.027 (-0.120, 0.066), 0.566		0.109 (0.019, 0.200), 0.017	
Flushing, n (%)	2 (6.1)	2 (3.3)	1 (2.6)	11 (13.6)	0.106
Odds Ratio (95% CIs) [1], P-Value		0.534 (0.072, 3.981), 0.535		5.814 (0.722, 46.798), 0.064	
Relative Risk (95% CIs) [2], P-Value		0.550 (0.081, 3.727), 0.540		5.160 (0.691, 38.534), 0.110	
Risk Difference (95% CIs) [2], P-Value		-0.027 (-0.120, 0.066), 0.566		0.109 (0.019, 0.200), 0.017	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Gastrointestinal disorders, n (%)	5 (17.9)	7 (13.5)	4 (26.7)	4 (21.1)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nausea, n (%)	4 (14.3)	5 (9.6)	4 (26.7)	3 (15.8)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Diarrhoea, n (%)	2 (7.1)	4 (7.7)	1 (6.7)	1 (5.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
General disorders and administration site conditions, n (%)	3 (10.7)	11 (21.2)	3 (20.0)	4 (21.1)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

	France		Spain	
System Organ Class Preferred Term	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=3)	Avapritinib 25 mg (N=14)
Gastrointestinal disorders, n (%)	1 (16.7)	2 (18.2)	0	2 (14.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nausea, n (%)	1 (16.7)	0	0	1 (7.1)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Diarrhoea, n (%)	0	2 (18.2)	0	2 (14.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
General disorders and administration site conditions, n (%)	0	1 (9.1)	0	4 (28.6)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

	United Kingdom		Canada	
System Organ Class Preferred Term	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=8)
Gastrointestinal disorders, n (%)	1 (20.0)	3 (27.3)	2 (40.0)	2 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nausea, n (%)	0	2 (18.2)	1 (20.0)	2 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Diarrhoea, n (%)	1 (20.0)	2 (18.2)	2 (40.0)	1 (12.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
General disorders and administration site conditions, n (%)	0	3 (27.3)	1 (20.0)	3 (37.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands		Norway	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)
Gastrointestinal disorders, n (%)	0	3 (33.3)	2 (66.7)	2 (40.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nausea, n (%)	0	1 (11.1)	2 (66.7)	2 (40.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Diarrhoea, n (%)	0	2 (22.2)	1 (33.3)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
General disorders and administration site conditions, n (%)	0	0	1 (33.3)	1 (20.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Gastrointestinal disorders, n (%)	0	1 (33.3)	0	1 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nausea, n (%)	0	1 (33.3)	0	1 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Diarrhoea, n (%)	0	0	0	1 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
General disorders and administration site conditions, n (%)	0	2 (66.7)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden		Switzerland	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=2)
Gastrointestinal disorders, n (%)	0	0	1 (100.0)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nausea, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Diarrhoea, n (%)	0	0	1 (100.0)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
General disorders and administration site conditions, n (%)	1 (100.0)	0	1 (100.0)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Gastrointestinal disorders, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Nausea, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Diarrhoea, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
General disorders and administration site conditions, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
General disorders and administration site conditions (cont.)	1 (3.6)	6 (11.5)	3 (20.0)	3 (15.8)
Fatigue, n (%)	1 (3.6)	6 (11.5)	3 (20.0)	3 (15.8)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	2 (7.1)	5 (9.6)	0	1 (5.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	2 (3.8)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Infections and infestations, n (%)	2 (7.1)	3 (5.8)	1 (6.7)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
General disorders and administration site conditions (cont.)	0	0	0	0
Fatigue, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	0	0	0	2 (14.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	1 (9.1)	0	2 (14.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Infections and infestations, n (%)	0	0	0	3 (21.4)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
General disorders and administration site conditions (cont.)	0	2 (18.2)	0	2 (25.0)
Fatigue, n (%)	0	2 (18.2)	0	2 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	0	1 (9.1)	0	1 (12.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	1 (9.1)	1 (20.0)	3 (37.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Infections and infestations, n (%)	2 (40.0)	2 (18.2)	1 (20.0)	1 (12.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
General disorders and administration site conditions (cont.)	0	0	1 (33.3)	0
Fatigue, n (%)	0	0	1 (33.3)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	0	0	0	1 (20.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Infections and infestations, n (%)	0	2 (22.2)	1 (33.3)	3 (60.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
General disorders and administration site conditions (cont.)	0	1 (33.3)	0	0
Fatigue, n (%)	0	1 (33.3)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	0	1 (33.3)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	1 (33.3)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Infections and infestations, n (%)	0	1 (33.3)	0	1 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=2)	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)
General disorders and administration site conditions (cont.)	0	0	1 (100.0)	0
Fatigue, n (%)	0	0	1 (100.0)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	1 (100.0)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Infections and infestations, n (%)	1 (100.0)	1 (50.0)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
General disorders and administration site conditions (cont.)	0	0	-
Fatigue, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Oedema peripheral, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Face oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Infections and infestations, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Infections and infestations (cont.)	2 (7.1)	3 (5.8)	1 (6.7)	0
COVID-19, n (%)	2 (7.1)	3 (5.8)	1 (6.7)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Musculoskeletal and connective tissue disorders, n (%)	3 (10.7)	2 (3.8)	0	1 (5.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Arthralgia, n (%)	3 (10.7)	2 (3.8)	0	1 (5.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nervous system disorders, n (%)	4 (14.3)	16 (30.8)	5 (33.3)	5 (26.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Infections and infestations (cont.)	0	0	0	3 (21.4)
COVID-19, n (%)	0	0	0	3 (21.4)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Musculoskeletal and connective tissue disorders, n (%)	1 (16.7)	2 (18.2)	0	1 (7.1)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Arthralgia, n (%)	1 (16.7)	2 (18.2)	0	1 (7.1)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nervous system disorders, n (%)	1 (16.7)	1 (9.1)	0	4 (28.6)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Infections and infestations (cont.)	2 (40.0)	2 (18.2)	1 (20.0)	1 (12.5)
COVID-19, n (%)	2 (40.0)	2 (18.2)	1 (20.0)	1 (12.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Musculoskeletal and connective tissue disorders, n (%)	1 (20.0)	1 (9.1)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Arthralgia, n (%)	1 (20.0)	1 (9.1)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nervous system disorders, n (%)	2 (40.0)	1 (9.1)	3 (60.0)	2 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Infections and infestations (cont.)	0	2 (22.2)	1 (33.3)	3 (60.0)
COVID-19, n (%)	0	2 (22.2)	1 (33.3)	3 (60.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Musculoskeletal and connective tissue disorders, n (%)	0	1 (11.1)	0	1 (20.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Arthralgia, n (%)	0	1 (11.1)	0	1 (20.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nervous system disorders, n (%)	0	3 (33.3)	1 (33.3)	2 (40.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Infections and infestations (cont.)	0	1 (33.3)	0	1 (25.0)
COVID-19, n (%)	0	1 (33.3)	0	1 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Musculoskeletal and connective tissue disorders, n (%)	0	1 (33.3)	0	1 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Arthralgia, n (%)	0	1 (33.3)	0	1 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nervous system disorders, n (%)	0	2 (66.7)	0	1 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=2)	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)
Infections and infestations (cont.)	1 (100.0)	1 (50.0)	0	0
COVID-19, n (%)	1 (100.0)	1 (50.0)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Musculoskeletal and connective tissue disorders, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Arthralgia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Nervous system disorders, n (%)	0	0	1 (100.0)	1 (50.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Infections and infestations (cont.)	0	0	-
COVID-19, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Musculoskeletal and connective tissue disorders, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Arthralgia, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Nervous system disorders, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

	United States		Germany	
System Organ Class Preferred Term	Placebo (N=28)	Avapritinib 25 mg (N=52)	Placebo (N=15)	Avapritinib 25 mg (N=19)
Nervous system disorders (cont.)	4 (14.3)	12 (23.1)	3 (20.0)	3 (15.8)
Headache, n (%)	4 (14.3)	12 (23.1)	3 (20.0)	3 (15.8)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dizziness, n (%)	1 (3.6)	6 (11.5)	3 (20.0)	3 (15.8)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Skin and subcutaneous tissue disorders, n (%)	0	4 (7.7)	1 (6.7)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Pruritus, n (%)	0	4 (7.7)	1 (6.7)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

	France		Spain	
System Organ Class Preferred Term	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=3)	Avapritinib 25 mg (N=14)
Nervous system disorders (cont.)	1 (16.7)	1 (9.1)	0	3 (21.4)
Headache, n (%)	1 (16.7)	1 (9.1)	0	3 (21.4)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dizziness, n (%)	0	0	0	1 (7.1)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Skin and subcutaneous tissue disorders, n (%)	1 (16.7)	0	0	1 (7.1)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Pruritus, n (%)	1 (16.7)	0	0	1 (7.1)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

	United Kingdom		Canada	
System Organ Class Preferred Term	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=8)
Nervous system disorders (cont.)	1 (20.0)	1 (9.1)	3 (60.0)	2 (25.0)
Headache, n (%)	1 (20.0)	1 (9.1)	3 (60.0)	2 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dizziness, n (%)	2 (40.0)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Skin and subcutaneous tissue disorders, n (%)	1 (20.0)	1 (9.1)	1 (20.0)	2 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Pruritus, n (%)	1 (20.0)	1 (9.1)	1 (20.0)	2 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Nervous system disorders (cont.)	0	1 (11.1)	1 (33.3)	2 (40.0)
Headache, n (%)	0	1 (11.1)	1 (33.3)	2 (40.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dizziness, n (%)	0	3 (33.3)	0	1 (20.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Skin and subcutaneous tissue disorders, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Pruritus, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Nervous system disorders (cont.)	0	2 (66.7)	0	0
Headache, n (%)	0	2 (66.7)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dizziness, n (%)	0	0	0	1 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Skin and subcutaneous tissue disorders, n (%)	1 (100.0)	2 (66.7)	0	1 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Pruritus, n (%)	1 (100.0)	2 (66.7)	0	1 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=2)	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)
Nervous system disorders (cont.)	0	0	1 (100.0)	0
Headache, n (%)	0	0	1 (100.0)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dizziness, n (%)	0	0	0	1 (50.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Skin and subcutaneous tissue disorders, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Pruritus, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Nervous system disorders (cont.)	0	0	-
Headache, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Dizziness, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Skin and subcutaneous tissue disorders, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Pruritus, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Vascular disorders, n (%)	1 (3.6)	0	0	2 (10.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Flushing, n (%)	1 (3.6)	0	0	2 (10.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Vascular disorders, n (%)	0	0	0	1 (7.1)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Flushing, n (%)	0	0	0	1 (7.1)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Vascular disorders, n (%)	0	3 (27.3)	1 (20.0)	2 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Flushing, n (%)	0	3 (27.3)	1 (20.0)	2 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Vascular disorders, n (%)	0	0	1 (33.3)	2 (40.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Flushing, n (%)	0	0	1 (33.3)	2 (40.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium		Italy	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=0)	Avapritinib 25 mg (N=4)
Vascular disorders, n (%)	0	2 (66.7)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Flushing, n (%)	0	2 (66.7)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden		Switzerland	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=2)
Vascular disorders, n (%)	0	0	0	1 (50.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Flushing, n (%)	0	0	0	1 (50.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.9a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Vascular disorders, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Flushing, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.2.1.1.1.1.4a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Gastrointestinal disorders, n (%)	7 (26.9)	9 (17.3)	9 (20.0)	18 (20.7)	0.407
Odds Ratio (95% CIs) [1], P-Value		0.568 (0.184, 1.751), 0.321		1.043 (0.426, 2.556), 0.926	
Relative Risk (95% CIs) [2], P-Value		0.643 (0.270, 1.532), 0.319		1.034 (0.506, 2.114), 0.926	
Risk Difference (95% CIs) [2], P-Value		-0.096 (-0.295, 0.103), 0.344		0.007 (-0.138, 0.151), 0.926	
Nausea, n (%)	6 (23.1)	5 (9.6)	6 (13.3)	13 (14.9)	0.168
Odds Ratio (95% CIs) [1], P-Value		0.355 (0.097, 1.297), 0.107		1.142 (0.403, 3.238), 0.803	
Relative Risk (95% CIs) [2], P-Value		0.417 (0.140, 1.239), 0.115		1.121 (0.457, 2.751), 0.804	
Risk Difference (95% CIs) [2], P-Value		-0.135 (-0.315, 0.046), 0.144		0.016 (-0.108, 0.140), 0.800	
Diarrhoea, n (%)	4 (15.4)	5 (9.6)	4 (8.9)	10 (11.5)	0.387
Odds Ratio (95% CIs) [1], P-Value		0.585 (0.143, 2.394), 0.452		1.331 (0.393, 4.508), 0.645	
Relative Risk (95% CIs) [2], P-Value		0.625 (0.183, 2.133), 0.453		1.293 (0.429, 3.894), 0.648	
Risk Difference (95% CIs) [2], P-Value		-0.058 (-0.218, 0.102), 0.480		0.026 (-0.081, 0.133), 0.633	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.4a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
General disorders and administration site conditions, n (%)	5 (19.2)	13 (25.0)	5 (11.1)	16 (18.4)	0.754
Odds Ratio (95% CIs) [1], P-Value		1.400 (0.439, 4.465), 0.569		1.803 (0.614, 5.289), 0.278	
Relative Risk (95% CIs) [2], P-Value		1.300 (0.519, 3.255), 0.575		1.655 (0.648, 4.227), 0.292	
Risk Difference (95% CIs) [2], P-Value		0.058 (-0.134, 0.250), 0.556		0.073 (-0.050, 0.196), 0.245	
Fatigue, n (%)	4 (15.4)	6 (11.5)	2 (4.4)	8 (9.2)	0.300
Odds Ratio (95% CIs) [1], P-Value		0.717 (0.184, 2.804), 0.632		2.177 (0.442, 10.713), 0.328	
Relative Risk (95% CIs) [2], P-Value		0.750 (0.232, 2.427), 0.631		2.069 (0.458, 9.339), 0.344	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.202, 0.125), 0.645		0.048 (-0.038, 0.133), 0.276	
Oedema peripheral, n (%)	1 (3.8)	5 (9.6)	2 (4.4)	7 (8.0)	0.804
Odds Ratio (95% CIs) [1], P-Value		2.660 (0.294, 24.031), 0.367		1.881 (0.374, 9.455), 0.436	
Relative Risk (95% CIs) [2], P-Value		2.500 (0.308, 20.309), 0.391		1.810 (0.392, 8.358), 0.447	
Risk Difference (95% CIs) [2], P-Value		0.058 (-0.051, 0.167), 0.300		0.036 (-0.047, 0.119), 0.395	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.4a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
General disorders and administration site conditions (cont.)					
Face oedema, n (%)	0	4 (7.7)	1 (2.2)	6 (6.9)	0.961
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.147		3.259 (0.380, 27.941), 0.256	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		3.103 (0.385, 24.996), 0.287	
Risk Difference (95% CIs) [2], P-Value		0.077 (0.004, 0.149), 0.037		0.047 (-0.022, 0.115), 0.181	
Infections and infestations, n (%)	1 (3.8)	3 (5.8)	7 (15.6)	14 (16.1)	0.764
Odds Ratio (95% CIs) [1], P-Value		1.531 (0.151, 15.480), 0.717		1.041 (0.387, 2.797), 0.936	
Relative Risk (95% CIs) [2], P-Value		1.500 (0.164, 13.724), 0.720		1.034 (0.450, 2.379), 0.936	
Risk Difference (95% CIs) [2], P-Value		0.019 (-0.078, 0.117), 0.699		0.005 (-0.126, 0.136), 0.936	
COVID-19, n (%)	1 (3.8)	3 (5.8)	7 (15.6)	14 (16.1)	0.764
Odds Ratio (95% CIs) [1], P-Value		1.531 (0.151, 15.480), 0.717		1.041 (0.387, 2.797), 0.936	
Relative Risk (95% CIs) [2], P-Value		1.500 (0.164, 13.724), 0.720		1.034 (0.450, 2.379), 0.936	
Risk Difference (95% CIs) [2], P-Value		0.019 (-0.078, 0.117), 0.699		0.005 (-0.126, 0.136), 0.936	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.4a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Musculoskeletal and connective tissue disorders, n (%)	1 (3.8)	5 (9.6)	4 (8.9)	6 (6.9)	0.338
Odds Ratio (95% CIs) [1], P-Value		2.660 (0.294, 24.031), 0.367		0.759 (0.203, 2.842), 0.682	
Relative Risk (95% CIs) [2], P-Value		2.500 (0.308, 20.309), 0.391		0.776 (0.231, 2.609), 0.682	
Risk Difference (95% CIs) [2], P-Value		0.058 (-0.051, 0.167), 0.300		-0.020 (-0.119, 0.079), 0.692	
Arthralgia, n (%)	1 (3.8)	5 (9.6)	4 (8.9)	6 (6.9)	0.338
Odds Ratio (95% CIs) [1], P-Value		2.660 (0.294, 24.031), 0.367		0.759 (0.203, 2.842), 0.682	
Relative Risk (95% CIs) [2], P-Value		2.500 (0.308, 20.309), 0.391		0.776 (0.231, 2.609), 0.682	
Risk Difference (95% CIs) [2], P-Value		0.058 (-0.051, 0.167), 0.300		-0.020 (-0.119, 0.079), 0.692	
Nervous system disorders, n (%)	6 (23.1)	12 (23.1)	11 (24.4)	26 (29.9)	0.697
Odds Ratio (95% CIs) [1], P-Value		1.000 (0.327, 3.057), >0.999		1.317 (0.580, 2.992), 0.509	
Relative Risk (95% CIs) [2], P-Value		1.000 (0.423, 2.362), >0.999		1.223 (0.667, 2.241), 0.516	
Risk Difference (95% CIs) [2], P-Value		0.000 (-0.198, 0.198), >0.999		0.054 (-0.104, 0.213), 0.500	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.4a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Nervous system disorders (cont.)					
Headache, n (%)	5 (19.2)	8 (15.4)	9 (20.0)	19 (21.8)	0.624
Odds Ratio (95% CIs) [1], P-Value		0.764 (0.223, 2.619), 0.667		1.118 (0.459, 2.722), 0.806	
Relative Risk (95% CIs) [2], P-Value		0.800 (0.290, 2.204), 0.666		1.092 (0.539, 2.214), 0.807	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.219, 0.142), 0.676		0.018 (-0.127, 0.164), 0.804	
Dizziness, n (%)	1 (3.8)	6 (11.5)	5 (11.1)	10 (11.5)	0.361
Odds Ratio (95% CIs) [1], P-Value		3.261 (0.371, 28.625), 0.262		1.039 (0.332, 3.247), 0.948	
Relative Risk (95% CIs) [2], P-Value		3.000 (0.381, 23.632), 0.297		1.034 (0.376, 2.844), 0.948	
Risk Difference (95% CIs) [2], P-Value		0.077 (-0.037, 0.191), 0.186		0.004 (-0.110, 0.118), 0.947	
Skin and subcutaneous tissue disorders, n (%)	1 (3.8)	3 (5.8)	4 (8.9)	8 (9.2)	0.773
Odds Ratio (95% CIs) [1], P-Value		1.531 (0.151, 15.480), 0.717		1.038 (0.295, 3.652), 0.954	
Relative Risk (95% CIs) [2], P-Value		1.500 (0.164, 13.724), 0.720		1.034 (0.329, 3.251), 0.954	
Risk Difference (95% CIs) [2], P-Value		0.019 (-0.078, 0.117), 0.699		0.003 (-0.100, 0.106), 0.953	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.4a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Skin and subcutaneous tissue disorders (cont.)					
Pruritus, n (%)	1 (3.8)	3 (5.8)	4 (8.9)	8 (9.2)	0.773
Odds Ratio (95% CIs) [1], P-Value		1.531 (0.151, 15.480), 0.717		1.038 (0.295, 3.652), 0.954	
Relative Risk (95% CIs) [2], P-Value		1.500 (0.164, 13.724), 0.720		1.034 (0.329, 3.251), 0.954	
Risk Difference (95% CIs) [2], P-Value		0.019 (-0.078, 0.117), 0.699		0.003 (-0.100, 0.106), 0.953	
Vascular disorders, n (%)	2 (7.7)	7 (13.5)	1 (2.2)	6 (6.9)	0.687
Odds Ratio (95% CIs) [1], P-Value		1.867 (0.359, 9.697), 0.452		3.259 (0.380, 27.941), 0.256	
Relative Risk (95% CIs) [2], P-Value		1.750 (0.391, 7.837), 0.464		3.103 (0.385, 24.996), 0.287	
Risk Difference (95% CIs) [2], P-Value		0.058 (-0.080, 0.196), 0.413		0.047 (-0.022, 0.115), 0.181	
Flushing, n (%)	2 (7.7)	7 (13.5)	1 (2.2)	6 (6.9)	0.687
Odds Ratio (95% CIs) [1], P-Value		1.867 (0.359, 9.697), 0.452		3.259 (0.380, 27.941), 0.256	
Relative Risk (95% CIs) [2], P-Value		1.750 (0.391, 7.837), 0.464		3.103 (0.385, 24.996), 0.287	
Risk Difference (95% CIs) [2], P-Value		0.058 (-0.080, 0.196), 0.413		0.047 (-0.022, 0.115), 0.181	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.5a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Gastrointestinal disorders, n (%)	4 (26.7)	8 (28.6)	12 (21.4)	19 (16.8)	0.633
Odds Ratio (95% CIs) [1], P-Value		1.100 (0.269, 4.496), 0.894		0.741 (0.331, 1.660), 0.466	
Relative Risk (95% CIs) [2], P-Value		1.071 (0.385, 2.981), 0.895		0.785 (0.411, 1.500), 0.463	
Risk Difference (95% CIs) [2], P-Value		0.019 (-0.260, 0.298), 0.894		-0.046 (-0.174, 0.082), 0.479	
Nausea, n (%)	3 (20.0)	7 (25.0)	9 (16.1)	11 (9.7)	0.347
Odds Ratio (95% CIs) [1], P-Value		1.333 (0.290, 6.140), 0.711		0.563 (0.219, 1.451), 0.230	
Relative Risk (95% CIs) [2], P-Value		1.250 (0.377, 4.143), 0.715		0.606 (0.267, 1.376), 0.231	
Risk Difference (95% CIs) [2], P-Value		0.050 (-0.208, 0.308), 0.704		-0.063 (-0.174, 0.047), 0.262	
Diarrhoea, n (%)	2 (13.3)	4 (14.3)	6 (10.7)	11 (9.7)	0.862
Odds Ratio (95% CIs) [1], P-Value		1.083 (0.174, 6.731), 0.932		0.899 (0.314, 2.570), 0.842	
Relative Risk (95% CIs) [2], P-Value		1.071 (0.221, 5.188), 0.932		0.909 (0.354, 2.330), 0.842	
Risk Difference (95% CIs) [2], P-Value		0.010 (-0.206, 0.225), 0.931		-0.010 (-0.108, 0.088), 0.844	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.5a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
General disorders and administration site conditions, n (%)	1 (6.7)	7 (25.0)	9 (16.1)	22 (19.5)	0.278
Odds Ratio (95% CIs) [1], P-Value		4.667 (0.516, 42.189), 0.141		1.263 (0.539, 2.959), 0.591	
Relative Risk (95% CIs) [2], P-Value		3.750 (0.508, 27.688), 0.195		1.211 (0.598, 2.455), 0.595	
Risk Difference (95% CIs) [2], P-Value		0.183 (-0.021, 0.387), 0.078		0.034 (-0.087, 0.155), 0.581	
Fatigue, n (%)	0	4 (14.3)	6 (10.7)	10 (8.8)	0.955
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.124		0.809 (0.278, 2.352), 0.697	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.826 (0.316, 2.157), 0.696	
Risk Difference (95% CIs) [2], P-Value		0.143 (0.013, 0.272), 0.031		-0.019 (-0.115, 0.078), 0.705	
Oedema peripheral, n (%)	1 (6.7)	2 (7.1)	2 (3.6)	10 (8.8)	0.552
Odds Ratio (95% CIs) [1], P-Value		1.077 (0.090, 12.948), 0.953		2.621 (0.554, 12.394), 0.209	
Relative Risk (95% CIs) [2], P-Value		1.071 (0.106, 10.871), 0.953		2.478 (0.562, 10.929), 0.231	
Risk Difference (95% CIs) [2], P-Value		0.005 (-0.153, 0.163), 0.953		0.053 (-0.019, 0.124), 0.148	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.5a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
General disorders and administration site conditions (cont.)					
Face oedema, n (%)	0	3 (10.7)	1 (1.8)	7 (6.2)	0.970
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.189		3.632 (0.436, 30.273), 0.204	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		3.469 (0.437, 27.510), 0.239	
Risk Difference (95% CIs) [2], P-Value		0.107 (-0.007, 0.222), 0.067		0.044 (-0.012, 0.100), 0.125	
Infections and infestations, n (%)	1 (6.7)	4 (14.3)	7 (12.5)	13 (11.5)	0.458
Odds Ratio (95% CIs) [1], P-Value		2.333 (0.237, 23.002), 0.458		0.910 (0.341, 2.426), 0.850	
Relative Risk (95% CIs) [2], P-Value		2.143 (0.262, 17.493), 0.477		0.920 (0.389, 2.178), 0.850	
Risk Difference (95% CIs) [2], P-Value		0.076 (-0.105, 0.257), 0.409		-0.010 (-0.115, 0.095), 0.852	
COVID-19, n (%)	1 (6.7)	4 (14.3)	7 (12.5)	13 (11.5)	0.458
Odds Ratio (95% CIs) [1], P-Value		2.333 (0.237, 23.002), 0.458		0.910 (0.341, 2.426), 0.850	
Relative Risk (95% CIs) [2], P-Value		2.143 (0.262, 17.493), 0.477		0.920 (0.389, 2.178), 0.850	
Risk Difference (95% CIs) [2], P-Value		0.076 (-0.105, 0.257), 0.409		-0.010 (-0.115, 0.095), 0.852	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.5a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Musculoskeletal and connective tissue disorders, n (%)	1 (6.7)	5 (17.9)	4 (7.1)	6 (5.3)	0.281
Odds Ratio (95% CIs) [1], P-Value		3.043 (0.322, 28.803), 0.313		0.729 (0.197, 2.696), 0.634	
Relative Risk (95% CIs) [2], P-Value		2.679 (0.344, 20.878), 0.347		0.743 (0.219, 2.528), 0.635	
Risk Difference (95% CIs) [2], P-Value		0.112 (-0.078, 0.302), 0.248		-0.018 (-0.097, 0.061), 0.650	
Arthralgia, n (%)	1 (6.7)	5 (17.9)	4 (7.1)	6 (5.3)	0.281
Odds Ratio (95% CIs) [1], P-Value		3.043 (0.322, 28.803), 0.313		0.729 (0.197, 2.696), 0.634	
Relative Risk (95% CIs) [2], P-Value		2.679 (0.344, 20.878), 0.347		0.743 (0.219, 2.528), 0.635	
Risk Difference (95% CIs) [2], P-Value		0.112 (-0.078, 0.302), 0.248		-0.018 (-0.097, 0.061), 0.650	
Nervous system disorders, n (%)	3 (20.0)	9 (32.1)	14 (25.0)	29 (25.7)	0.477
Odds Ratio (95% CIs) [1], P-Value		1.895 (0.426, 8.434), 0.398		1.036 (0.495, 2.166), 0.926	
Relative Risk (95% CIs) [2], P-Value		1.607 (0.511, 5.057), 0.417		1.027 (0.591, 1.782), 0.926	
Risk Difference (95% CIs) [2], P-Value		0.121 (-0.145, 0.388), 0.371		0.007 (-0.132, 0.146), 0.925	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.5a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Nervous system disorders (cont.)					
Headache, n (%)	3 (20.0)	7 (25.0)	11 (19.6)	20 (17.7)	0.638
Odds Ratio (95% CIs) [1], P-Value		1.333 (0.290, 6.140), 0.711		0.880 (0.389, 1.992), 0.759	
Relative Risk (95% CIs) [2], P-Value		1.250 (0.377, 4.143), 0.715		0.901 (0.465, 1.747), 0.758	
Risk Difference (95% CIs) [2], P-Value		0.050 (-0.208, 0.308), 0.704		-0.019 (-0.145, 0.106), 0.762	
Dizziness, n (%)	1 (6.7)	4 (14.3)	5 (8.9)	12 (10.6)	0.613
Odds Ratio (95% CIs) [1], P-Value		2.333 (0.237, 23.002), 0.458		1.212 (0.405, 3.627), 0.731	
Relative Risk (95% CIs) [2], P-Value		2.143 (0.262, 17.493), 0.477		1.189 (0.441, 3.210), 0.732	
Risk Difference (95% CIs) [2], P-Value		0.076 (-0.105, 0.257), 0.409		0.017 (-0.077, 0.111), 0.724	
Skin and subcutaneous tissue disorders, n (%)	3 (20.0)	2 (7.1)	2 (3.6)	9 (8.0)	0.108
Odds Ratio (95% CIs) [1], P-Value		0.308 (0.045, 2.089), 0.210		2.337 (0.488, 11.198), 0.276	
Relative Risk (95% CIs) [2], P-Value		0.357 (0.067, 1.908), 0.228		2.230 (0.498, 9.978), 0.294	
Risk Difference (95% CIs) [2], P-Value		-0.129 (-0.352, 0.095), 0.260		0.044 (-0.026, 0.114), 0.217	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.5a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Skin and subcutaneous tissue disorders (cont.)					
Pruritus, n (%)	3 (20.0)	2 (7.1)	2 (3.6)	9 (8.0)	0.108
Odds Ratio (95% CIs) [1], P-Value		0.308 (0.045, 2.089), 0.210		2.337 (0.488, 11.198), 0.276	
Relative Risk (95% CIs) [2], P-Value		0.357 (0.067, 1.908), 0.228		2.230 (0.498, 9.978), 0.294	
Risk Difference (95% CIs) [2], P-Value		-0.129 (-0.352, 0.095), 0.260		0.044 (-0.026, 0.114), 0.217	
Vascular disorders, n (%)	0	3 (10.7)	3 (5.4)	10 (8.8)	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.189		1.715 (0.453, 6.499), 0.423	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.652 (0.473, 5.765), 0.431	
Risk Difference (95% CIs) [2], P-Value		0.107 (-0.007, 0.222), 0.067		0.035 (-0.044, 0.114), 0.385	
Flushing, n (%)	0	3 (10.7)	3 (5.4)	10 (8.8)	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.189		1.715 (0.453, 6.499), 0.423	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.652 (0.473, 5.765), 0.431	
Risk Difference (95% CIs) [2], P-Value		0.107 (-0.007, 0.222), 0.067		0.035 (-0.044, 0.114), 0.385	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.6a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Gastrointestinal disorders, n (%)	9 (25.7)	15 (20.8)	7 (19.4)	12 (17.4)	0.848
Odds Ratio (95% CIs) [1], P-Value		0.760 (0.295, 1.961), 0.570		0.872 (0.310, 2.452), 0.795	
Relative Risk (95% CIs) [2], P-Value		0.810 (0.394, 1.666), 0.567		0.894 (0.386, 2.073), 0.795	
Risk Difference (95% CIs) [2], P-Value		-0.049 (-0.221, 0.124), 0.579		-0.021 (-0.178, 0.137), 0.798	
Nausea, n (%)	8 (22.9)	9 (12.5)	4 (11.1)	9 (13.0)	0.275
Odds Ratio (95% CIs) [1], P-Value		0.482 (0.168, 1.383), 0.169		1.200 (0.343, 4.203), 0.775	
Relative Risk (95% CIs) [2], P-Value		0.547 (0.231, 1.296), 0.170		1.174 (0.388, 3.550), 0.776	
Risk Difference (95% CIs) [2], P-Value		-0.104 (-0.262, 0.055), 0.201		0.019 (-0.110, 0.149), 0.770	
Diarrhoea, n (%)	3 (8.6)	7 (9.7)	5 (13.9)	8 (11.6)	0.715
Odds Ratio (95% CIs) [1], P-Value		1.149 (0.278, 4.739), 0.848		0.813 (0.245, 2.694), 0.735	
Relative Risk (95% CIs) [2], P-Value		1.134 (0.312, 4.124), 0.848		0.835 (0.294, 2.367), 0.734	
Risk Difference (95% CIs) [2], P-Value		0.012 (-0.104, 0.127), 0.845		-0.023 (-0.159, 0.113), 0.741	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.6a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
General disorders and administration site conditions, n (%)	5 (14.3)	16 (22.2)	5 (13.9)	13 (18.8)	0.827
Odds Ratio (95% CIs) [1], P-Value		1.714 (0.572, 5.138), 0.332		1.439 (0.469, 4.415), 0.523	
Relative Risk (95% CIs) [2], P-Value		1.556 (0.620, 3.901), 0.346		1.357 (0.525, 3.506), 0.529	
Risk Difference (95% CIs) [2], P-Value		0.079 (-0.071, 0.230), 0.301		0.050 (-0.096, 0.195), 0.506	
Fatigue, n (%)	4 (11.4)	7 (9.7)	2 (5.6)	7 (10.1)	0.433
Odds Ratio (95% CIs) [1], P-Value		0.835 (0.227, 3.065), 0.785		1.919 (0.377, 9.759), 0.425	
Relative Risk (95% CIs) [2], P-Value		0.851 (0.267, 2.714), 0.785		1.826 (0.400, 8.340), 0.437	
Risk Difference (95% CIs) [2], P-Value		-0.017 (-0.143, 0.109), 0.790		0.046 (-0.057, 0.149), 0.384	
Oedema peripheral, n (%)	1 (2.9)	5 (6.9)	2 (5.6)	7 (10.1)	0.841
Odds Ratio (95% CIs) [1], P-Value		2.537 (0.285, 22.589), 0.389		1.919 (0.377, 9.759), 0.425	
Relative Risk (95% CIs) [2], P-Value		2.431 (0.295, 20.022), 0.409		1.826 (0.400, 8.340), 0.437	
Risk Difference (95% CIs) [2], P-Value		0.041 (-0.040, 0.121), 0.320		0.046 (-0.057, 0.149), 0.384	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.6a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	Number of Baseline BSC <4 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	Number of Baseline BSC >=4 Avapritinib 25 mg (N=69)	P-Value [3]
General disorders and administration site conditions (cont.)					
Face oedema, n (%)	0	5 (6.9)	1 (2.8)	5 (7.2)	0.955
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.110		2.734 (0.307, 24.340), 0.349	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.609 (0.317, 21.493), 0.373	
Risk Difference (95% CIs) [2], P-Value		0.069 (0.011, 0.128), 0.020		0.045 (-0.037, 0.126), 0.282	
Infections and infestations, n (%)	2 (5.7)	8 (11.1)	6 (16.7)	9 (13.0)	0.311
Odds Ratio (95% CIs) [1], P-Value		2.063 (0.414, 10.271), 0.368		0.750 (0.244, 2.304), 0.615	
Relative Risk (95% CIs) [2], P-Value		1.944 (0.436, 8.679), 0.384		0.783 (0.302, 2.026), 0.613	
Risk Difference (95% CIs) [2], P-Value		0.054 (-0.052, 0.160), 0.317		-0.036 (-0.182, 0.109), 0.625	
COVID-19, n (%)	2 (5.7)	8 (11.1)	6 (16.7)	9 (13.0)	0.311
Odds Ratio (95% CIs) [1], P-Value		2.063 (0.414, 10.271), 0.368		0.750 (0.244, 2.304), 0.615	
Relative Risk (95% CIs) [2], P-Value		1.944 (0.436, 8.679), 0.384		0.783 (0.302, 2.026), 0.613	
Risk Difference (95% CIs) [2], P-Value		0.054 (-0.052, 0.160), 0.317		-0.036 (-0.182, 0.109), 0.625	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.6a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Musculoskeletal and connective tissue disorders, n (%)	1 (2.9)	8 (11.1)	4 (11.1)	3 (4.3)	0.067
Odds Ratio (95% CIs) [1], P-Value		4.250 (0.510, 35.409), 0.149		0.364 (0.077, 1.722), 0.187	
Relative Risk (95% CIs) [2], P-Value		3.889 (0.506, 29.885), 0.192		0.391 (0.093, 1.654), 0.202	
Risk Difference (95% CIs) [2], P-Value		0.083 (-0.009, 0.174), 0.076		-0.068 (-0.181, 0.046), 0.242	
Arthralgia, n (%)	1 (2.9)	8 (11.1)	4 (11.1)	3 (4.3)	0.067
Odds Ratio (95% CIs) [1], P-Value		4.250 (0.510, 35.409), 0.149		0.364 (0.077, 1.722), 0.187	
Relative Risk (95% CIs) [2], P-Value		3.889 (0.506, 29.885), 0.192		0.391 (0.093, 1.654), 0.202	
Risk Difference (95% CIs) [2], P-Value		0.083 (-0.009, 0.174), 0.076		-0.068 (-0.181, 0.046), 0.242	
Nervous system disorders, n (%)	11 (31.4)	18 (25.0)	6 (16.7)	20 (29.0)	0.135
Odds Ratio (95% CIs) [1], P-Value		0.727 (0.298, 1.773), 0.483		2.041 (0.736, 5.655), 0.165	
Relative Risk (95% CIs) [2], P-Value		0.795 (0.423, 1.497), 0.478		1.739 (0.767, 3.943), 0.185	
Risk Difference (95% CIs) [2], P-Value		-0.064 (-0.248, 0.119), 0.492		0.123 (-0.039, 0.285), 0.136	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.6a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Nervous system disorders (cont.)					
Headache, n (%)	9 (25.7)	15 (20.8)	5 (13.9)	12 (17.4)	0.473
Odds Ratio (95% CIs) [1], P-Value		0.760 (0.295, 1.961), 0.570		1.305 (0.421, 4.046), 0.644	
Relative Risk (95% CIs) [2], P-Value		0.810 (0.394, 1.666), 0.567		1.252 (0.478, 3.278), 0.647	
Risk Difference (95% CIs) [2], P-Value		-0.049 (-0.221, 0.124), 0.579		0.035 (-0.109, 0.179), 0.634	
Dizziness, n (%)	4 (11.4)	5 (6.9)	2 (5.6)	11 (15.9)	0.107
Odds Ratio (95% CIs) [1], P-Value		0.578 (0.145, 2.304), 0.433		3.224 (0.674, 15.420), 0.125	
Relative Risk (95% CIs) [2], P-Value		0.608 (0.174, 2.123), 0.435		2.870 (0.672, 12.255), 0.155	
Risk Difference (95% CIs) [2], P-Value		-0.045 (-0.165, 0.076), 0.466		0.104 (-0.010, 0.218), 0.075	
Skin and subcutaneous tissue disorders, n (%)	3 (8.6)	3 (4.2)	2 (5.6)	8 (11.6)	0.182
Odds Ratio (95% CIs) [1], P-Value		0.464 (0.089, 2.425), 0.353		2.230 (0.448, 11.101), 0.317	
Relative Risk (95% CIs) [2], P-Value		0.486 (0.103, 2.287), 0.361		2.087 (0.467, 9.317), 0.335	
Risk Difference (95% CIs) [2], P-Value		-0.044 (-0.148, 0.060), 0.405		0.060 (-0.046, 0.167), 0.266	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.6a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Skin and subcutaneous tissue disorders (cont.)					
Pruritus, n (%)	3 (8.6)	3 (4.2)	2 (5.6)	8 (11.6)	0.182
Odds Ratio (95% CIs) [1], P-Value		0.464 (0.089, 2.425), 0.353		2.230 (0.448, 11.101), 0.317	
Relative Risk (95% CIs) [2], P-Value		0.486 (0.103, 2.287), 0.361		2.087 (0.467, 9.317), 0.335	
Risk Difference (95% CIs) [2], P-Value		-0.044 (-0.148, 0.060), 0.405		0.060 (-0.046, 0.167), 0.266	
Vascular disorders, n (%)	1 (2.9)	7 (9.7)	2 (5.6)	6 (8.7)	0.554
Odds Ratio (95% CIs) [1], P-Value		3.662 (0.433, 30.996), 0.205		1.619 (0.310, 8.462), 0.565	
Relative Risk (95% CIs) [2], P-Value		3.403 (0.435, 26.591), 0.243		1.565 (0.333, 7.365), 0.571	
Risk Difference (95% CIs) [2], P-Value		0.069 (-0.019, 0.157), 0.126		0.031 (-0.069, 0.131), 0.539	
Flushing, n (%)	1 (2.9)	7 (9.7)	2 (5.6)	6 (8.7)	0.554
Odds Ratio (95% CIs) [1], P-Value		3.662 (0.433, 30.996), 0.205		1.619 (0.310, 8.462), 0.565	
Relative Risk (95% CIs) [2], P-Value		3.403 (0.435, 26.591), 0.243		1.565 (0.333, 7.365), 0.571	
Risk Difference (95% CIs) [2], P-Value		0.069 (-0.019, 0.157), 0.126		0.031 (-0.069, 0.131), 0.539	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.7a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Gastrointestinal disorders, n (%)	1 (14.3)	2 (10.5)	15 (23.4)	25 (20.5)	0.897
Odds Ratio (95% CIs) [1], P-Value		0.706 (0.054, 9.265), 0.790		0.842 (0.407, 1.741), 0.642	
Relative Risk (95% CIs) [2], P-Value		0.737 (0.079, 6.912), 0.789		0.874 (0.497, 1.537), 0.641	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.331, 0.256), 0.802		-0.029 (-0.156, 0.097), 0.647	
Nausea, n (%)	0	1 (5.3)	12 (18.8)	17 (13.9)	0.951
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.536		0.702 (0.312, 1.578), 0.390	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.743 (0.379, 1.458), 0.388	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		-0.048 (-0.162, 0.066), 0.406	
Diarrhoea, n (%)	1 (14.3)	2 (10.5)	7 (10.9)	13 (10.7)	0.820
Odds Ratio (95% CIs) [1], P-Value		0.706 (0.054, 9.265), 0.790		0.971 (0.367, 2.570), 0.953	
Relative Risk (95% CIs) [2], P-Value		0.737 (0.079, 6.912), 0.789		0.974 (0.409, 2.320), 0.953	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.331, 0.256), 0.802		-0.003 (-0.097, 0.091), 0.953	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.7a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes		No		P-Value [3]
	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	
General disorders and administration site conditions, n (%)	0	2 (10.5)	10 (15.6)	27 (22.1)	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.372		1.535 (0.690, 3.411), 0.291	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.416 (0.732, 2.739), 0.301	
Risk Difference (95% CIs) [2], P-Value		0.105 (-0.033, 0.243), 0.135		0.065 (-0.050, 0.181), 0.270	
Fatigue, n (%)	0	1 (5.3)	6 (9.4)	13 (10.7)	0.960
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.536		1.153 (0.416, 3.192), 0.784	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.137 (0.453, 2.849), 0.785	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		0.013 (-0.077, 0.103), 0.780	
Oedema peripheral, n (%)	0	2 (10.5)	3 (4.7)	10 (8.2)	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.372		1.815 (0.481, 6.846), 0.373	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.749 (0.499, 6.129), 0.383	
Risk Difference (95% CIs) [2], P-Value		0.105 (-0.033, 0.243), 0.135		0.035 (-0.036, 0.106), 0.333	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.7a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes		No		P-Value [3]
	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	
General disorders and administration site conditions (cont.)					
Face oedema, n (%)	0	2 (10.5)	1 (1.6)	8 (6.6)	0.956
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.372		4.421 (0.541, 36.157), 0.132	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		4.197 (0.537, 32.820), 0.172	
Risk Difference (95% CIs) [2], P-Value		0.105 (-0.033, 0.243), 0.135		0.050 (-0.003, 0.103), 0.067	
Infections and infestations, n (%)	1 (14.3)	1 (5.3)	7 (10.9)	16 (13.1)	0.405
Odds Ratio (95% CIs) [1], P-Value		0.333 (0.018, 6.191), 0.444		1.229 (0.478, 3.161), 0.668	
Relative Risk (95% CIs) [2], P-Value		0.368 (0.026, 5.126), 0.457		1.199 (0.520, 2.764), 0.670	
Risk Difference (95% CIs) [2], P-Value		-0.090 (-0.368, 0.188), 0.525		0.022 (-0.075, 0.119), 0.660	
COVID-19, n (%)	1 (14.3)	1 (5.3)	7 (10.9)	16 (13.1)	0.405
Odds Ratio (95% CIs) [1], P-Value		0.333 (0.018, 6.191), 0.444		1.229 (0.478, 3.161), 0.668	
Relative Risk (95% CIs) [2], P-Value		0.368 (0.026, 5.126), 0.457		1.199 (0.520, 2.764), 0.670	
Risk Difference (95% CIs) [2], P-Value		-0.090 (-0.368, 0.188), 0.525		0.022 (-0.075, 0.119), 0.660	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.7a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Musculoskeletal and connective tissue disorders, n (%)	1 (14.3)	2 (10.5)	4 (6.3)	9 (7.4)	0.717
Odds Ratio (95% CIs) [1], P-Value		0.706 (0.054, 9.265), 0.790		1.195 (0.353, 4.041), 0.775	
Relative Risk (95% CIs) [2], P-Value		0.737 (0.079, 6.912), 0.789		1.180 (0.378, 3.684), 0.775	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.331, 0.256), 0.802		0.011 (-0.064, 0.087), 0.769	
Arthralgia, n (%)	1 (14.3)	2 (10.5)	4 (6.3)	9 (7.4)	0.717
Odds Ratio (95% CIs) [1], P-Value		0.706 (0.054, 9.265), 0.790		1.195 (0.353, 4.041), 0.775	
Relative Risk (95% CIs) [2], P-Value		0.737 (0.079, 6.912), 0.789		1.180 (0.378, 3.684), 0.775	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.331, 0.256), 0.802		0.011 (-0.064, 0.087), 0.769	
Nervous system disorders, n (%)	1 (14.3)	2 (10.5)	16 (25.0)	36 (29.5)	0.672
Odds Ratio (95% CIs) [1], P-Value		0.706 (0.054, 9.265), 0.790		1.256 (0.632, 2.495), 0.515	
Relative Risk (95% CIs) [2], P-Value		0.737 (0.079, 6.912), 0.789		1.180 (0.712, 1.956), 0.520	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.331, 0.256), 0.802		0.045 (-0.088, 0.179), 0.508	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.7a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Nervous system disorders (cont.)					
Headache, n (%)	1 (14.3)	1 (5.3)	13 (20.3)	26 (21.3)	0.451
Odds Ratio (95% CIs) [1], P-Value		0.333 (0.018, 6.191), 0.444		1.063 (0.503, 2.243), 0.874	
Relative Risk (95% CIs) [2], P-Value		0.368 (0.026, 5.126), 0.457		1.049 (0.580, 1.899), 0.874	
Risk Difference (95% CIs) [2], P-Value		-0.090 (-0.368, 0.188), 0.525		0.010 (-0.112, 0.132), 0.873	
Dizziness, n (%)	0	1 (5.3)	6 (9.4)	15 (12.3)	0.959
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.536		1.355 (0.499, 3.681), 0.550	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.311 (0.535, 3.216), 0.554	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		0.029 (-0.063, 0.121), 0.535	
Skin and subcutaneous tissue disorders, n (%)	2 (28.6)	2 (10.5)	3 (4.7)	9 (7.4)	0.194
Odds Ratio (95% CIs) [1], P-Value		0.294 (0.033, 2.652), 0.258		1.619 (0.423, 6.205), 0.478	
Relative Risk (95% CIs) [2], P-Value		0.368 (0.064, 2.137), 0.266		1.574 (0.441, 5.610), 0.484	
Risk Difference (95% CIs) [2], P-Value		-0.180 (-0.542, 0.182), 0.329		0.027 (-0.043, 0.096), 0.448	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.7a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Skin and subcutaneous tissue disorders (cont.)					
Pruritus, n (%)	2 (28.6)	2 (10.5)	3 (4.7)	9 (7.4)	0.194
Odds Ratio (95% CIs) [1], P-Value		0.294 (0.033, 2.652), 0.258		1.619 (0.423, 6.205), 0.478	
Relative Risk (95% CIs) [2], P-Value		0.368 (0.064, 2.137), 0.266		1.574 (0.441, 5.610), 0.484	
Risk Difference (95% CIs) [2], P-Value		-0.180 (-0.542, 0.182), 0.329		0.027 (-0.043, 0.096), 0.448	
Vascular disorders, n (%)	0	1 (5.3)	3 (4.7)	12 (9.8)	0.966
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.536		2.218 (0.603, 8.166), 0.221	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.098 (0.614, 7.168), 0.237	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		0.051 (-0.023, 0.125), 0.173	
Flushing, n (%)	0	1 (5.3)	3 (4.7)	12 (9.8)	0.966
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.536		2.218 (0.603, 8.166), 0.221	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.098 (0.614, 7.168), 0.237	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		0.051 (-0.023, 0.125), 0.173	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.8a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes		No		P-Value [3]
	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	
Gastrointestinal disorders, n (%)	1 (9.1)	6 (23.1)	15 (25.0)	21 (18.3)	0.215
Odds Ratio (95% CIs) [1], P-Value		3.000 (0.317, 28.434), 0.321		0.670 (0.316, 1.421), 0.295	
Relative Risk (95% CIs) [2], P-Value		2.538 (0.345, 18.685), 0.360		0.730 (0.407, 1.310), 0.292	
Risk Difference (95% CIs) [2], P-Value		0.140 (-0.095, 0.375), 0.243		-0.067 (-0.198, 0.063), 0.311	
Nausea, n (%)	1 (9.1)	5 (19.2)	11 (18.3)	13 (11.3)	0.249
Odds Ratio (95% CIs) [1], P-Value		2.381 (0.245, 23.168), 0.444		0.568 (0.237, 1.358), 0.199	
Relative Risk (95% CIs) [2], P-Value		2.115 (0.278, 16.075), 0.469		0.617 (0.294, 1.292), 0.200	
Risk Difference (95% CIs) [2], P-Value		0.101 (-0.126, 0.329), 0.383		-0.070 (-0.184, 0.043), 0.226	
Diarrhoea, n (%)	0	4 (15.4)	8 (13.3)	11 (9.6)	0.959
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.168		0.688 (0.261, 1.813), 0.447	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.717 (0.305, 1.688), 0.447	
Risk Difference (95% CIs) [2], P-Value		0.154 (0.015, 0.293), 0.030		-0.038 (-0.139, 0.064), 0.467	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.8a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
General disorders and administration site conditions, n (%)	0	5 (19.2)	10 (16.7)	24 (20.9)	0.952
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.118		1.319 (0.584, 2.977), 0.505	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.252 (0.642, 2.443), 0.510	
Risk Difference (95% CIs) [2], P-Value		0.192 (0.041, 0.344), 0.013		0.042 (-0.078, 0.162), 0.493	
Fatigue, n (%)	0	3 (11.5)	6 (10.0)	11 (9.6)	0.945
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.240		0.952 (0.334, 2.714), 0.927	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.957 (0.372, 2.460), 0.927	
Risk Difference (95% CIs) [2], P-Value		0.115 (-0.007, 0.238), 0.066		-0.004 (-0.097, 0.089), 0.927	
Oedema peripheral, n (%)	0	2 (7.7)	3 (5.0)	10 (8.7)	0.955
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.344		1.810 (0.479, 6.841), 0.376	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.739 (0.497, 6.082), 0.386	
Risk Difference (95% CIs) [2], P-Value		0.077 (-0.026, 0.179), 0.141		0.037 (-0.038, 0.112), 0.337	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.8a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
General disorders and administration site conditions (cont.)					
Face oedema, n (%)	0	4 (15.4)	1 (1.7)	6 (5.2)	0.960
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.168		3.248 (0.382, 27.620), 0.255	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		3.130 (0.386, 25.407), 0.285	
Risk Difference (95% CIs) [2], P-Value		0.154 (0.015, 0.293), 0.030		0.036 (-0.016, 0.087), 0.181	
Infections and infestations, n (%)	1 (9.1)	5 (19.2)	7 (11.7)	12 (10.4)	0.433
Odds Ratio (95% CIs) [1], P-Value		2.381 (0.245, 23.168), 0.444		0.882 (0.328, 2.372), 0.804	
Relative Risk (95% CIs) [2], P-Value		2.115 (0.278, 16.075), 0.469		0.894 (0.372, 2.153), 0.803	
Risk Difference (95% CIs) [2], P-Value		0.101 (-0.126, 0.329), 0.383		-0.012 (-0.111, 0.086), 0.807	
COVID-19, n (%)	1 (9.1)	5 (19.2)	7 (11.7)	12 (10.4)	0.433
Odds Ratio (95% CIs) [1], P-Value		2.381 (0.245, 23.168), 0.444		0.882 (0.328, 2.372), 0.804	
Relative Risk (95% CIs) [2], P-Value		2.115 (0.278, 16.075), 0.469		0.894 (0.372, 2.153), 0.803	
Risk Difference (95% CIs) [2], P-Value		0.101 (-0.126, 0.329), 0.383		-0.012 (-0.111, 0.086), 0.807	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.8a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
Musculoskeletal and connective tissue disorders, n (%)	0	2 (7.7)	5 (8.3)	9 (7.8)	0.951
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.344		0.934 (0.298, 2.922), 0.907	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.939 (0.329, 2.678), 0.906	
Risk Difference (95% CIs) [2], P-Value		0.077 (-0.026, 0.179), 0.141		-0.005 (-0.091, 0.080), 0.907	
Arthralgia, n (%)	0	2 (7.7)	5 (8.3)	9 (7.8)	0.951
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.344		0.934 (0.298, 2.922), 0.907	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.939 (0.329, 2.678), 0.906	
Risk Difference (95% CIs) [2], P-Value		0.077 (-0.026, 0.179), 0.141		-0.005 (-0.091, 0.080), 0.907	
Nervous system disorders, n (%)	1 (9.1)	6 (23.1)	16 (26.7)	32 (27.8)	0.387
Odds Ratio (95% CIs) [1], P-Value		3.000 (0.317, 28.434), 0.321		1.060 (0.525, 2.141), 0.870	
Relative Risk (95% CIs) [2], P-Value		2.538 (0.345, 18.685), 0.360		1.043 (0.625, 1.742), 0.871	
Risk Difference (95% CIs) [2], P-Value		0.140 (-0.095, 0.375), 0.243		0.012 (-0.127, 0.150), 0.870	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.8a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
Nervous system disorders (cont.)					
Headache, n (%)	0	3 (11.5)	14 (23.3)	24 (20.9)	0.952
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.240		0.867 (0.410, 1.832), 0.707	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.894 (0.501, 1.598), 0.706	
Risk Difference (95% CIs) [2], P-Value		0.115 (-0.007, 0.238), 0.066		-0.025 (-0.155, 0.106), 0.711	
Dizziness, n (%)	1 (9.1)	3 (11.5)	5 (8.3)	13 (11.3)	0.957
Odds Ratio (95% CIs) [1], P-Value		1.304 (0.120, 14.119), 0.827		1.402 (0.475, 4.138), 0.539	
Relative Risk (95% CIs) [2], P-Value		1.269 (0.148, 10.902), 0.828		1.357 (0.508, 3.625), 0.543	
Risk Difference (95% CIs) [2], P-Value		0.024 (-0.185, 0.234), 0.819		0.030 (-0.061, 0.120), 0.521	
Skin and subcutaneous tissue disorders, n (%)	0	2 (7.7)	5 (8.3)	9 (7.8)	0.951
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.344		0.934 (0.298, 2.922), 0.907	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.939 (0.329, 2.678), 0.906	
Risk Difference (95% CIs) [2], P-Value		0.077 (-0.026, 0.179), 0.141		-0.005 (-0.091, 0.080), 0.907	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.2.1.1.1.1.8a
Summary of Adverse Events Occurred >= 1 % and >= 10 Patients in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
Skin and subcutaneous tissue disorders (cont.)					
Pruritus, n (%)	0	2 (7.7)	5 (8.3)	9 (7.8)	0.951
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.344		0.934 (0.298, 2.922), 0.907	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.939 (0.329, 2.678), 0.906	
Risk Difference (95% CIs) [2], P-Value		0.077 (-0.026, 0.179), 0.141		-0.005 (-0.091, 0.080), 0.907	
Vascular disorders, n (%)	0	5 (19.2)	3 (5.0)	8 (7.0)	0.948
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.118		1.421 (0.363, 5.564), 0.613	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.391 (0.383, 5.053), 0.616	
Risk Difference (95% CIs) [2], P-Value		0.192 (0.041, 0.344), 0.013		0.020 (-0.053, 0.092), 0.595	
Flushing, n (%)	0	5 (19.2)	3 (5.0)	8 (7.0)	0.948
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.118		1.421 (0.363, 5.564), 0.613	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.391 (0.383, 5.053), 0.616	
Risk Difference (95% CIs) [2], P-Value		0.192 (0.041, 0.344), 0.013		0.020 (-0.053, 0.092), 0.595	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-ge1p10n-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.3.1.1.1a
Summary of Serious Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sae-socpt-ge5p-subgrp-a.sas Date: 17:19/05MAY2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.3.1.1.2a
Summary of Serious Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sae-socpt-ge5p-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.3.1.1.3a
Summary of Serious Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sae-socpt-ge5p-subgrp-a.sas Date: 17:19/05MAY2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.3.1.1.9a
Summary of Serious Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sae-socpt-ge5p-country-a.sas Date: 11:52/20JUL2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.3.1.1.4a
Summary of Serious Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sae-socpt-ge5p-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.3.1.1.5a
Summary of Serious Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sae-socpt-ge5p-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.3.1.1.6a
Summary of Serious Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sae-socpt-ge5p-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.3.1.1.7a
Summary of Serious Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sae-socpt-ge5p-subgrp-a.sas Date: 17:19/05MAY2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.3.1.1.8a
Summary of Serious Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sae-socpt-ge5p-subgrp-a.sas Date: 17:19/05MAY2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.4.1.1.1a
Summary of Grade 3 or Higher Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-grd3-ge5p-subgrp-a.sas Date: 17:17/05MAY2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.4.1.1.2a
Summary of Grade 3 or Higher Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-grd3-ge5p-subgrp-a.sas Date: 17:17/05MAY2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.4.1.1.3a
Summary of Grade 3 or Higher Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-grd3-ge5p-subgrp-a.sas Date: 17:17/05MAY2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.4.1.1.9a
Summary of Grade 3 or Higher Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-grd3-ge5p-country-a.sas Date: 11:52/20JUL2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.4.1.1.4a
Summary of Grade 3 or Higher Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-grd3-ge5p-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.4.1.1.5a
Summary of Grade 3 or Higher Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-grd3-ge5p-subgrp-a.sas Date: 17:17/05MAY2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.4.1.1.6a
Summary of Grade 3 or Higher Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-grd3-ge5p-subgrp-a.sas Date: 17:17/05MAY2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.4.1.1.7a
Summary of Grade 3 or Higher Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-grd3-ge5p-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.4.1.1.8a
Summary of Grade 3 or Higher Adverse Events Occurred >= 5 % in at Least One Treatment Group by System Organ Class and Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/system organ class.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-socpt-grd3-ge5p-subgrp-a.sas Date: 17:17/05MAY2023

Table 35.3.1.11.1.1.1a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Patients with at least one AESI, n (%)	2 (3.3)	4 (3.0)	1 (9.1)	0	0.952
Odds Ratio (95% CIs) [1], P-Value		0.906 (0.161, 5.089), 0.911		NE (NE, NE), 0.353	
Relative Risk (95% CIs) [2], P-Value		0.909 (0.171, 4.828), 0.911		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.003 (-0.057, 0.051), 0.912		-0.091 (-0.261, 0.079), 0.294	
Cognitive Effects, n (%)	2 (3.3)	4 (3.0)	1 (9.1)	0	0.952
Odds Ratio (95% CIs) [1], P-Value		0.906 (0.161, 5.089), 0.911		NE (NE, NE), 0.353	
Relative Risk (95% CIs) [2], P-Value		0.909 (0.171, 4.828), 0.911		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.003 (-0.057, 0.051), 0.912		-0.091 (-0.261, 0.079), 0.294	
Memory impairment, n (%)	1 (1.7)	2 (1.5)	0	0	>0.999
Odds Ratio (95% CIs) [1], P-Value		0.908 (0.081, 10.209), 0.937		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.909 (0.084, 9.832), 0.937		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.002 (-0.040, 0.037), 0.939		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.1a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	1 (0.8)	0	0	0.982
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.499		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.008 (-0.007, 0.022), 0.315		NA (NA, NA), NA	
Mood altered, n (%)	0	1 (0.8)	0	0	0.982
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.499		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.008 (-0.007, 0.022), 0.315		NA (NA, NA), NA	
Mental impairment, n (%)	1 (1.7)	0	0	0	0.981
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.137		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.017 (-0.049, 0.016), 0.313		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.1a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Cognitive Effects (cont.)					
Mental status changes, n (%)	0	0	1 (9.1)	0	0.965
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.353	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.091 (-0.261, 0.079), 0.294	
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.1a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.1a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.1a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.1a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.1a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.2a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Patients with at least one AESI, n (%)	1 (5.9)	1 (2.4)	2 (3.7)	3 (3.0)	0.684
Odds Ratio (95% CIs) [1], P-Value		0.400 (0.024, 6.790), 0.513		0.804 (0.130, 4.966), 0.814	
Relative Risk (95% CIs) [2], P-Value		0.415 (0.027, 6.254), 0.525		0.810 (0.140, 4.700), 0.814	
Risk Difference (95% CIs) [2], P-Value		-0.034 (-0.156, 0.087), 0.578		-0.007 (-0.067, 0.053), 0.820	
Cognitive Effects, n (%)	1 (5.9)	1 (2.4)	2 (3.7)	3 (3.0)	0.684
Odds Ratio (95% CIs) [1], P-Value		0.400 (0.024, 6.790), 0.513		0.804 (0.130, 4.966), 0.814	
Relative Risk (95% CIs) [2], P-Value		0.415 (0.027, 6.254), 0.525		0.810 (0.140, 4.700), 0.814	
Risk Difference (95% CIs) [2], P-Value		-0.034 (-0.156, 0.087), 0.578		-0.007 (-0.067, 0.053), 0.820	
Memory impairment, n (%)	1 (5.9)	1 (2.4)	0	1 (1.0)	0.949
Odds Ratio (95% CIs) [1], P-Value		0.400 (0.024, 6.790), 0.513		NE (NE, NE), 0.461	
Relative Risk (95% CIs) [2], P-Value		0.415 (0.027, 6.254), 0.525		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.034 (-0.156, 0.087), 0.578		0.010 (-0.010, 0.030), 0.315	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.2a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	0	0	1 (1.0)	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.461	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.010, 0.030), 0.315	
Mood altered, n (%)	0	0	0	1 (1.0)	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.461	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.010, 0.030), 0.315	
Mental impairment, n (%)	0	0	1 (1.9)	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.172	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.054, 0.017), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.2a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Cognitive Effects (cont.)					
Mental status changes, n (%)	0	0	1 (1.9)	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.172	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.054, 0.017), 0.313	
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.2a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.2a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.2a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.2a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.2a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.3a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Patients with at least one AESI, n (%)	2 (6.1)	2 (3.3)	1 (2.6)	2 (2.5)	0.727
Odds Ratio (95% CIs) [1], P-Value		0.534 (0.072, 3.981), 0.535		0.937 (0.082, 10.661), 0.958	
Relative Risk (95% CIs) [2], P-Value		0.550 (0.081, 3.727), 0.540		0.938 (0.088, 10.030), 0.958	
Risk Difference (95% CIs) [2], P-Value		-0.027 (-0.120, 0.066), 0.566		-0.002 (-0.063, 0.059), 0.958	
Cognitive Effects, n (%)	2 (6.1)	2 (3.3)	1 (2.6)	2 (2.5)	0.727
Odds Ratio (95% CIs) [1], P-Value		0.534 (0.072, 3.981), 0.535		0.937 (0.082, 10.661), 0.958	
Relative Risk (95% CIs) [2], P-Value		0.550 (0.081, 3.727), 0.540		0.938 (0.088, 10.030), 0.958	
Risk Difference (95% CIs) [2], P-Value		-0.027 (-0.120, 0.066), 0.566		-0.002 (-0.063, 0.059), 0.958	
Memory impairment, n (%)	1 (3.0)	2 (3.3)	0	0	>0.999
Odds Ratio (95% CIs) [1], P-Value		1.103 (0.096, 12.647), 0.937		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		1.100 (0.104, 11.680), 0.937		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.003 (-0.071, 0.077), 0.936		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.3a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	0	0	1 (1.2)	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.492	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.012 (-0.012, 0.036), 0.314	
Mood altered, n (%)	0	0	0	1 (1.2)	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.492	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.012 (-0.012, 0.036), 0.314	
Mental impairment, n (%)	0	0	1 (2.6)	0	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.143	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.026 (-0.077, 0.025), 0.311	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.3a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Cognitive Effects (cont.)					
Mental status changes, n (%)	1 (3.0)	0	0	0	0.969
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.175		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.030 (-0.089, 0.028), 0.310		NA (NA, NA), NA	
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.3a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.3a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.3a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.3a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.3a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Cognitive Effects, n (%)	2 (7.1)	2 (3.8)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	1 (3.6)	2 (3.8)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Cognitive Effects, n (%)	0	0	0	1 (7.1)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	1 (7.1)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects, n (%)	1 (20.0)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Cognitive Effects, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden		Switzerland	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=2)
Cognitive Effects, n (%)	0	0	0	1 (50.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	1 (50.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Memory impairment, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Amnesia, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Mood altered, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	1 (3.6)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	1 (20.0)	0	0	0
Mental impairment, n (%)	1 (20.0)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=2)	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Mental impairment, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Mental status changes, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Agitation, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Cognitive Effects (cont.)	0	0	0	0
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Cognitive Effects (cont.)	0	0	0	0
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	0	0	0	0
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Cognitive Effects (cont.)	0	0	0	0
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=2)	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)
Cognitive Effects (cont.)	0	0	0	0
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Confusional state, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Delirium, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Dementia, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Disorientation, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Cognitive Effects (cont.)	0	0	0	0
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Cognitive Effects (cont.)	0	0	0	0
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	0	0	0	0
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Cognitive Effects (cont.)	0	0	0	0
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden		Switzerland	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=2)
Cognitive Effects (cont.)	0	0	0	0
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Encephalopathy, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Hallucination, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Personality change, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=2)	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Somnolence, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Speech disorder, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=2)	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.9a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Intracranial Bleeding (cont.)	0	0	-
Cerebral haemorrhage, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.1.1.4a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Patients with at least one AESI, n (%)	2 (7.7)	1 (1.9)	1 (2.2)	3 (3.4)	0.267
Odds Ratio (95% CIs) [1], P-Value		0.235 (0.020, 2.724), 0.212		1.571 (0.159, 15.555), 0.697	
Relative Risk (95% CIs) [2], P-Value		0.250 (0.024, 2.631), 0.248		1.552 (0.166, 14.494), 0.700	
Risk Difference (95% CIs) [2], P-Value		-0.058 (-0.167, 0.051), 0.300		0.012 (-0.045, 0.070), 0.677	
Cognitive Effects, n (%)	2 (7.7)	1 (1.9)	1 (2.2)	3 (3.4)	0.267
Odds Ratio (95% CIs) [1], P-Value		0.235 (0.020, 2.724), 0.212		1.571 (0.159, 15.555), 0.697	
Relative Risk (95% CIs) [2], P-Value		0.250 (0.024, 2.631), 0.248		1.552 (0.166, 14.494), 0.700	
Risk Difference (95% CIs) [2], P-Value		-0.058 (-0.167, 0.051), 0.300		0.012 (-0.045, 0.070), 0.677	
Memory impairment, n (%)	1 (3.8)	1 (1.9)	0	1 (1.1)	0.955
Odds Ratio (95% CIs) [1], P-Value		0.490 (0.029, 8.165), 0.612		NE (NE, NE), 0.470	
Relative Risk (95% CIs) [2], P-Value		0.500 (0.033, 7.678), 0.619		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.019 (-0.102, 0.064), 0.649		0.011 (-0.011, 0.034), 0.315	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.4a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	0	0	1 (1.1)	0.968
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.470	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.011 (-0.011, 0.034), 0.315	
Mood altered, n (%)	0	0	0	1 (1.1)	0.968
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.470	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.011 (-0.011, 0.034), 0.315	
Mental impairment, n (%)	0	0	1 (2.2)	0	0.962
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.163	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.022 (-0.065, 0.021), 0.312	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.4a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Cognitive Effects (cont.)					
Mental status changes, n (%)	1 (3.8)	0	0	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.155		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.112, 0.035), 0.308		NA (NA, NA), NA	
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.4a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.4a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.4a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.4a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.4a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.5a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Patients with at least one AESI, n (%)	1 (6.7)	0	2 (3.6)	4 (3.5)	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.167		0.991 (0.176, 5.580), 0.992	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.991 (0.187, 5.249), 0.992	
Risk Difference (95% CIs) [2], P-Value		-0.067 (-0.193, 0.060), 0.301		-0.000 (-0.060, 0.059), 0.992	
Cognitive Effects, n (%)	1 (6.7)	0	2 (3.6)	4 (3.5)	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.167		0.991 (0.176, 5.580), 0.992	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.991 (0.187, 5.249), 0.992	
Risk Difference (95% CIs) [2], P-Value		-0.067 (-0.193, 0.060), 0.301		-0.000 (-0.060, 0.059), 0.992	
Memory impairment, n (%)	1 (6.7)	0	0	2 (1.8)	0.929
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.167		NE (NE, NE), 0.317	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.067 (-0.193, 0.060), 0.301		0.018 (-0.007, 0.042), 0.154	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.5a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	0	0	1 (0.9)	0.975
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.480	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.009 (-0.008, 0.026), 0.315	
Mood altered, n (%)	0	0	0	1 (0.9)	0.975
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.480	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.009 (-0.008, 0.026), 0.315	
Mental impairment, n (%)	0	0	1 (1.8)	0	0.971
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.154	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.018 (-0.053, 0.017), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.5a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Cognitive Effects (cont.)					
Mental status changes, n (%)	0	0	1 (1.8)	0	0.971
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.154	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.018 (-0.053, 0.017), 0.313	
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.5a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.5a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.5a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.5a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.5a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.6a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Patients with at least one AESI, n (%)	0	0	3 (8.3)	4 (5.8)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.677 (0.143, 3.204), 0.621	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.696 (0.165, 2.941), 0.622	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.025 (-0.131, 0.080), 0.638	
Cognitive Effects, n (%)	0	0	3 (8.3)	4 (5.8)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.677 (0.143, 3.204), 0.621	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.696 (0.165, 2.941), 0.622	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.025 (-0.131, 0.080), 0.638	
Memory impairment, n (%)	0	0	1 (2.8)	2 (2.9)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.045 (0.092, 11.927), 0.972	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.043 (0.098, 11.122), 0.972	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.001 (-0.065, 0.068), 0.972	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.6a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	0	0	1 (1.4)	0.965
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.014 (-0.014, 0.043), 0.314	
Mood altered, n (%)	0	0	0	1 (1.4)	0.965
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.014 (-0.014, 0.043), 0.314	
Mental impairment, n (%)	0	0	1 (2.8)	0	0.956
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.164	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.028 (-0.081, 0.026), 0.310	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.6a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Cognitive Effects (cont.)					
Mental status changes, n (%)	0	0	1 (2.8)	0	0.956
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.164	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.028 (-0.081, 0.026), 0.310	
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.6a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.6a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.6a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.6a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.6a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.7a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Patients with at least one AESI, n (%)	0	1 (5.3)	3 (4.7)	3 (2.5)	0.957
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.536		0.513 (0.100, 2.616), 0.414	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.525 (0.109, 2.525), 0.421	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		-0.022 (-0.081, 0.036), 0.456	
Cognitive Effects, n (%)	0	1 (5.3)	3 (4.7)	3 (2.5)	0.957
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.536		0.513 (0.100, 2.616), 0.414	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.525 (0.109, 2.525), 0.421	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		-0.022 (-0.081, 0.036), 0.456	
Memory impairment, n (%)	0	0	1 (1.6)	2 (1.6)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.050 (0.093, 11.805), 0.968	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.049 (0.097, 11.351), 0.968	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.001 (-0.037, 0.039), 0.968	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.7a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	0	0	1 (0.8)	0.981
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.008 (-0.008, 0.024), 0.315	
Mood altered, n (%)	0	1 (5.3)	0	0	0.959
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.536		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	1 (1.6)	0	0.980
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.166	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.016 (-0.046, 0.015), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.7a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Cognitive Effects (cont.)					
Mental status changes, n (%)	0	0	1 (1.6)	0	0.980
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.166	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.016 (-0.046, 0.015), 0.313	
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.7a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.7a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.7a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.7a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.7a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.8a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
Patients with at least one AESI, n (%)	0	1 (3.8)	3 (5.0)	3 (2.6)	0.948
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.510		0.509 (0.100, 2.602), 0.409	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.522 (0.109, 2.507), 0.417	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.035, 0.112), 0.308		-0.024 (-0.086, 0.038), 0.452	
Cognitive Effects, n (%)	0	1 (3.8)	3 (5.0)	3 (2.6)	0.948
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.510		0.509 (0.100, 2.602), 0.409	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.522 (0.109, 2.507), 0.417	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.035, 0.112), 0.308		-0.024 (-0.086, 0.038), 0.452	
Memory impairment, n (%)	0	0	1 (1.7)	2 (1.7)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.044 (0.093, 11.755), 0.972	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.043 (0.097, 11.276), 0.972	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.001 (-0.040, 0.041), 0.972	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.8a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	0	0	1 (0.9)	0.977
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.469	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.009 (-0.008, 0.026), 0.315	
Mood altered, n (%)	0	1 (3.8)	0	0	0.956
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.510		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.035, 0.112), 0.308		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	1 (1.7)	0	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.165	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.017 (-0.049, 0.016), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.8a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
Cognitive Effects (cont.)					
Mental status changes, n (%)	0	0	1 (1.7)	0	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.165	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.017 (-0.049, 0.016), 0.313	
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.8a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.8a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.8a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.8a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.11.1.1.8a
Summary of Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.12.1.1.1a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Patients with at least one Serious AESI, n (%)	0	0	1 (9.1)	0	0.965
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.353	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.091 (-0.261, 0.079), 0.294	
Cognitive Effects, n (%)	0	0	1 (9.1)	0	0.965
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.353	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.091 (-0.261, 0.079), 0.294	
Mental status changes, n (%)	0	0	1 (9.1)	0	0.965
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.353	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.091 (-0.261, 0.079), 0.294	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.1a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.1a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.1a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.1a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.1a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.1a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.1a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.2a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Patients with at least one Serious AESI, n (%)	0	0	1 (1.9)	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.172	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.054, 0.017), 0.313	
Cognitive Effects, n (%)	0	0	1 (1.9)	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.172	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.054, 0.017), 0.313	
Mental status changes, n (%)	0	0	1 (1.9)	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.172	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.054, 0.017), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.2a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.2a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.2a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.2a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.2a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.2a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.2a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.3a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Patients with at least one Serious AESI, n (%)	1 (3.0)	0	0	0	0.969
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.175		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.030 (-0.089, 0.028), 0.310		NA (NA, NA), NA	
Cognitive Effects, n (%)	1 (3.0)	0	0	0	0.969
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.175		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.030 (-0.089, 0.028), 0.310		NA (NA, NA), NA	
Mental status changes, n (%)	1 (3.0)	0	0	0	0.969
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.175		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.030 (-0.089, 0.028), 0.310		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.3a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.3a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.3a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.3a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.3a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.3a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.3a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Cognitive Effects, n (%)	1 (3.6)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	1 (3.6)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Cognitive Effects, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

	Netherlands		Norway	
System Organ Class Preferred Term	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)
Cognitive Effects, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Cognitive Effects, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=2)	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)
Cognitive Effects, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Mental status changes, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Agitation, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Amnesia, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Cognitive Effects (cont.)	0	0	0	0
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Cognitive Effects (cont.)	0	0	0	0
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	0	0	0	0
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Cognitive Effects (cont.)	0	0	0	0
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=2)	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)
Cognitive Effects (cont.)	0	0	0	0
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Cognitive disorder, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Confusional state, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Delirium, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Dementia, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Cognitive Effects (cont.)	0	0	0	0
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Cognitive Effects (cont.)	0	0	0	0
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	0	0	0	0
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Cognitive Effects (cont.)	0	0	0	0
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=2)	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)
Cognitive Effects (cont.)	0	0	0	0
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Disorientation, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Hallucination, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Memory impairment, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=2)	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Mental impairment, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Mood altered, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Personality change, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=2)	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Somnolence, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Speech disorder, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=2)	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.9a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Intracranial Bleeding (cont.)	0	0	-
Cerebral haemorrhage, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.12.1.1.4a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Patients with at least one Serious AESI, n (%)	1 (3.8)	0	0	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.155		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.112, 0.035), 0.308		NA (NA, NA), NA	
Cognitive Effects, n (%)	1 (3.8)	0	0	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.155		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.112, 0.035), 0.308		NA (NA, NA), NA	
Mental status changes, n (%)	1 (3.8)	0	0	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.155		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.112, 0.035), 0.308		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.4a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.4a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.4a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.4a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.4a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.4a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.4a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.5a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Patients with at least one Serious AESI, n (%)	0	0	1 (1.8)	0	0.971
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.154	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.018 (-0.053, 0.017), 0.313	
Cognitive Effects, n (%)	0	0	1 (1.8)	0	0.971
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.154	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.018 (-0.053, 0.017), 0.313	
Mental status changes, n (%)	0	0	1 (1.8)	0	0.971
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.154	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.018 (-0.053, 0.017), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.5a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.5a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.5a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.5a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.5a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.5a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.5a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.6a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Patients with at least one Serious AESI, n (%)	0	0	1 (2.8)	0	0.956
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.164	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.028 (-0.081, 0.026), 0.310	
Cognitive Effects, n (%)	0	0	1 (2.8)	0	0.956
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.164	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.028 (-0.081, 0.026), 0.310	
Mental status changes, n (%)	0	0	1 (2.8)	0	0.956
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.164	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.028 (-0.081, 0.026), 0.310	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.6a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.6a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.6a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.6a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.6a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.6a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.6a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.7a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Patients with at least one Serious AESI, n (%)	0	0	1 (1.6)	0	0.980
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.166	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.016 (-0.046, 0.015), 0.313	
Cognitive Effects, n (%)	0	0	1 (1.6)	0	0.980
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.166	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.016 (-0.046, 0.015), 0.313	
Mental status changes, n (%)	0	0	1 (1.6)	0	0.980
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.166	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.016 (-0.046, 0.015), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.7a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.7a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes		No		P-Value [3]
	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.7a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes		No		P-Value [3]
	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.7a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes		No		P-Value [3]
	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.7a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes		No		P-Value [3]
	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.7a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.7a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.8a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
Patients with at least one Serious AESI, n (%)	0	0	1 (1.7)	0	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.165	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.017 (-0.049, 0.016), 0.313	
Cognitive Effects, n (%)	0	0	1 (1.7)	0	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.165	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.017 (-0.049, 0.016), 0.313	
Mental status changes, n (%)	0	0	1 (1.7)	0	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.165	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.017 (-0.049, 0.016), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.8a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.8a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.8a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes		No		P-Value [3]
	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.8a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes		No		P-Value [3]
	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.8a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes		No		P-Value [3]
	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.8a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.12.1.1.8a
Summary of Serious Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-saesi-subgrp-a.sas Date: 17:20/05MAY2023

Table 35.3.1.11.2.1.1a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Patients with at least one Grade 1 an 2 AESI, n (%)	2 (3.3)	4 (3.0)	0	0	>0.999
Odds Ratio (95% CIs) [1], P-Value		0.906 (0.161, 5.089), 0.911		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.909 (0.171, 4.828), 0.911		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.003 (-0.057, 0.051), 0.912		NA (NA, NA), NA	
Cognitive Effects, n (%)	2 (3.3)	4 (3.0)	0	0	>0.999
Odds Ratio (95% CIs) [1], P-Value		0.906 (0.161, 5.089), 0.911		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.909 (0.171, 4.828), 0.911		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.003 (-0.057, 0.051), 0.912		NA (NA, NA), NA	
Memory impairment, n (%)	1 (1.7)	2 (1.5)	0	0	>0.999
Odds Ratio (95% CIs) [1], P-Value		0.908 (0.081, 10.209), 0.937		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.909 (0.084, 9.832), 0.937		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.002 (-0.040, 0.037), 0.939		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.1a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	1 (0.8)	0	0	0.982
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.499		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.008 (-0.007, 0.022), 0.315		NA (NA, NA), NA	
Mood altered, n (%)	0	1 (0.8)	0	0	0.982
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.499		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.008 (-0.007, 0.022), 0.315		NA (NA, NA), NA	
Mental impairment, n (%)	1 (1.7)	0	0	0	0.981
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.137		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.017 (-0.049, 0.016), 0.313		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.1a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.1a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Cognitive Effects (cont.)					
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.1a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Cognitive Effects (cont.)					
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental status changes, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.1a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.1a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.1a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.2a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Patients with at least one Grade 1 an 2 AESI, n (%)	1 (5.9)	1 (2.4)	1 (1.9)	3 (3.0)	0.448
Odds Ratio (95% CIs) [1], P-Value		0.400 (0.024, 6.790), 0.513		1.639 (0.166, 16.151), 0.669	
Relative Risk (95% CIs) [2], P-Value		0.415 (0.027, 6.254), 0.525		1.620 (0.173, 15.200), 0.673	
Risk Difference (95% CIs) [2], P-Value		-0.034 (-0.156, 0.087), 0.578		0.011 (-0.038, 0.061), 0.647	
Cognitive Effects, n (%)	1 (5.9)	1 (2.4)	1 (1.9)	3 (3.0)	0.448
Odds Ratio (95% CIs) [1], P-Value		0.400 (0.024, 6.790), 0.513		1.639 (0.166, 16.151), 0.669	
Relative Risk (95% CIs) [2], P-Value		0.415 (0.027, 6.254), 0.525		1.620 (0.173, 15.200), 0.673	
Risk Difference (95% CIs) [2], P-Value		-0.034 (-0.156, 0.087), 0.578		0.011 (-0.038, 0.061), 0.647	
Memory impairment, n (%)	1 (5.9)	1 (2.4)	0	1 (1.0)	0.949
Odds Ratio (95% CIs) [1], P-Value		0.400 (0.024, 6.790), 0.513		NE (NE, NE), 0.461	
Relative Risk (95% CIs) [2], P-Value		0.415 (0.027, 6.254), 0.525		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.034 (-0.156, 0.087), 0.578		0.010 (-0.010, 0.030), 0.315	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.2a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	0	0	1 (1.0)	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.461	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.010, 0.030), 0.315	
Mood altered, n (%)	0	0	0	1 (1.0)	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.461	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.010, 0.030), 0.315	
Mental impairment, n (%)	0	0	1 (1.9)	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.172	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.054, 0.017), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.2a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.2a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Cognitive Effects (cont.)					
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.2a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Cognitive Effects (cont.)					
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental status changes, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.2a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.2a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.2a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.3a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Patients with at least one Grade 1 an 2 AESI, n (%)	1 (3.0)	2 (3.3)	1 (2.6)	2 (2.5)	0.926
Odds Ratio (95% CIs) [1], P-Value		1.103 (0.096, 12.647), 0.937		0.937 (0.082, 10.661), 0.958	
Relative Risk (95% CIs) [2], P-Value		1.100 (0.104, 11.680), 0.937		0.938 (0.088, 10.030), 0.958	
Risk Difference (95% CIs) [2], P-Value		0.003 (-0.071, 0.077), 0.936		-0.002 (-0.063, 0.059), 0.958	
Cognitive Effects, n (%)	1 (3.0)	2 (3.3)	1 (2.6)	2 (2.5)	0.926
Odds Ratio (95% CIs) [1], P-Value		1.103 (0.096, 12.647), 0.937		0.937 (0.082, 10.661), 0.958	
Relative Risk (95% CIs) [2], P-Value		1.100 (0.104, 11.680), 0.937		0.938 (0.088, 10.030), 0.958	
Risk Difference (95% CIs) [2], P-Value		0.003 (-0.071, 0.077), 0.936		-0.002 (-0.063, 0.059), 0.958	
Memory impairment, n (%)	1 (3.0)	2 (3.3)	0	0	>0.999
Odds Ratio (95% CIs) [1], P-Value		1.103 (0.096, 12.647), 0.937		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		1.100 (0.104, 11.680), 0.937		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.003 (-0.071, 0.077), 0.936		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.3a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	0	0	1 (1.2)	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.492	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.012 (-0.012, 0.036), 0.314	
Mood altered, n (%)	0	0	0	1 (1.2)	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.492	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.012 (-0.012, 0.036), 0.314	
Mental impairment, n (%)	0	0	1 (2.6)	0	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.143	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.026 (-0.077, 0.025), 0.311	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.3a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.3a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Cognitive Effects (cont.)					
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.3a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Cognitive Effects (cont.)					
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental status changes, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.3a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.3a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.3a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Cognitive Effects, n (%)	1 (3.6)	2 (3.8)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	1 (3.6)	2 (3.8)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Cognitive Effects, n (%)	0	0	0	1 (7.1)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	1 (7.1)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects, n (%)	1 (20.0)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium		Italy	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=0)	Avapritinib 25 mg (N=4)
Cognitive Effects, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden		Switzerland	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=2)
Cognitive Effects, n (%)	0	0	0	1 (50.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	1 (50.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Memory impairment, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Amnesia, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Mood altered, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	1 (20.0)	0	0	0
Mental impairment, n (%)	1 (20.0)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

	Belgium		Italy	
System Organ Class Preferred Term	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=0)	Avapritinib 25 mg (N=4)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=2)	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Mental impairment, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Agitation, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Confusional state, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Cognitive Effects (cont.)	0	0	0	0
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Cognitive Effects (cont.)	0	0	0	0
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	0	0	0	0
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Cognitive Effects (cont.)	0	0	0	0
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=2)	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)
Cognitive Effects (cont.)	0	0	0	0
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Delirium, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Dementia, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Disorientation, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Cognitive Effects (cont.)	0	0	0	0
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Cognitive Effects (cont.)	0	0	0	0
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	0	0	0	0
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Cognitive Effects (cont.)	0	0	0	0
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=2)	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)
Cognitive Effects (cont.)	0	0	0	0
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Hallucination, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Mental status changes, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Personality change, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=2)	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Somnolence, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Speech disorder, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=2)	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.9a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Intracranial Bleeding (cont.)	0	0	-
Cerebral haemorrhage, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.2.1.4a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Patients with at least one Grade 1 an 2 AESI, n (%)	1 (3.8)	1 (1.9)	1 (2.2)	3 (3.4)	0.529
Odds Ratio (95% CIs) [1], P-Value		0.490 (0.029, 8.165), 0.612		1.571 (0.159, 15.555), 0.697	
Relative Risk (95% CIs) [2], P-Value		0.500 (0.033, 7.678), 0.619		1.552 (0.166, 14.494), 0.700	
Risk Difference (95% CIs) [2], P-Value		-0.019 (-0.102, 0.064), 0.649		0.012 (-0.045, 0.070), 0.677	
Cognitive Effects, n (%)	1 (3.8)	1 (1.9)	1 (2.2)	3 (3.4)	0.529
Odds Ratio (95% CIs) [1], P-Value		0.490 (0.029, 8.165), 0.612		1.571 (0.159, 15.555), 0.697	
Relative Risk (95% CIs) [2], P-Value		0.500 (0.033, 7.678), 0.619		1.552 (0.166, 14.494), 0.700	
Risk Difference (95% CIs) [2], P-Value		-0.019 (-0.102, 0.064), 0.649		0.012 (-0.045, 0.070), 0.677	
Memory impairment, n (%)	1 (3.8)	1 (1.9)	0	1 (1.1)	0.955
Odds Ratio (95% CIs) [1], P-Value		0.490 (0.029, 8.165), 0.612		NE (NE, NE), 0.470	
Relative Risk (95% CIs) [2], P-Value		0.500 (0.033, 7.678), 0.619		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.019 (-0.102, 0.064), 0.649		0.011 (-0.011, 0.034), 0.315	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.4a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	0	0	1 (1.1)	0.968
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.470	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.011 (-0.011, 0.034), 0.315	
Mood altered, n (%)	0	0	0	1 (1.1)	0.968
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.470	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.011 (-0.011, 0.034), 0.315	
Mental impairment, n (%)	0	0	1 (2.2)	0	0.962
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.163	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.022 (-0.065, 0.021), 0.312	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.4a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.4a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Cognitive Effects (cont.)					
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.4a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Cognitive Effects (cont.)					
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental status changes, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.4a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.4a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.4a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.5a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Patients with at least one Grade 1 an 2 AESI, n (%)	1 (6.7)	0	1 (1.8)	4 (3.5)	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.167		2.018 (0.220, 18.494), 0.526	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.982 (0.227, 17.323), 0.536	
Risk Difference (95% CIs) [2], P-Value		-0.067 (-0.193, 0.060), 0.301		0.018 (-0.031, 0.066), 0.479	
Cognitive Effects, n (%)	1 (6.7)	0	1 (1.8)	4 (3.5)	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.167		2.018 (0.220, 18.494), 0.526	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.982 (0.227, 17.323), 0.536	
Risk Difference (95% CIs) [2], P-Value		-0.067 (-0.193, 0.060), 0.301		0.018 (-0.031, 0.066), 0.479	
Memory impairment, n (%)	1 (6.7)	0	0	2 (1.8)	0.929
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.167		NE (NE, NE), 0.317	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.067 (-0.193, 0.060), 0.301		0.018 (-0.007, 0.042), 0.154	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.5a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	0	0	1 (0.9)	0.975
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.480	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.009 (-0.008, 0.026), 0.315	
Mood altered, n (%)	0	0	0	1 (0.9)	0.975
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.480	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.009 (-0.008, 0.026), 0.315	
Mental impairment, n (%)	0	0	1 (1.8)	0	0.971
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.154	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.018 (-0.053, 0.017), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.5a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.5a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Cognitive Effects (cont.)					
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.5a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Cognitive Effects (cont.)					
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental status changes, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.5a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.5a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.5a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.6a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Patients with at least one Grade 1 an 2 AESI, n (%)	0	0	2 (5.6)	4 (5.8)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.046 (0.182, 6.004), 0.960	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.043 (0.201, 5.427), 0.960	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.002 (-0.091, 0.095), 0.959	
Cognitive Effects, n (%)	0	0	2 (5.6)	4 (5.8)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.046 (0.182, 6.004), 0.960	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.043 (0.201, 5.427), 0.960	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.002 (-0.091, 0.095), 0.959	
Memory impairment, n (%)	0	0	1 (2.8)	2 (2.9)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.045 (0.092, 11.927), 0.972	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.043 (0.098, 11.122), 0.972	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.001 (-0.065, 0.068), 0.972	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.6a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	0	0	1 (1.4)	0.965
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.014 (-0.014, 0.043), 0.314	
Mood altered, n (%)	0	0	0	1 (1.4)	0.965
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.014 (-0.014, 0.043), 0.314	
Mental impairment, n (%)	0	0	1 (2.8)	0	0.956
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.164	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.028 (-0.081, 0.026), 0.310	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.6a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.6a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Cognitive Effects (cont.)					
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.6a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Cognitive Effects (cont.)					
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental status changes, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.6a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.6a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.6a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.7a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Patients with at least one Grade 1 an 2 AESI, n (%)	0	1 (5.3)	2 (3.1)	3 (2.5)	0.961
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.536		0.782 (0.127, 4.801), 0.790	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.787 (0.135, 4.589), 0.790	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		-0.007 (-0.057, 0.044), 0.797	
Cognitive Effects, n (%)	0	1 (5.3)	2 (3.1)	3 (2.5)	0.961
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.536		0.782 (0.127, 4.801), 0.790	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.787 (0.135, 4.589), 0.790	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		-0.007 (-0.057, 0.044), 0.797	
Memory impairment, n (%)	0	0	1 (1.6)	2 (1.6)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.050 (0.093, 11.805), 0.968	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.049 (0.097, 11.351), 0.968	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.001 (-0.037, 0.039), 0.968	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.7a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	0	0	1 (0.8)	0.981
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.008 (-0.008, 0.024), 0.315	
Mood altered, n (%)	0	1 (5.3)	0	0	0.959
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.536		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	1 (1.6)	0	0.980
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.166	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.016 (-0.046, 0.015), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.7a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.7a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Cognitive Effects (cont.)					
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.7a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Cognitive Effects (cont.)					
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental status changes, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.7a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.7a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.7a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes		No		P-Value [3]
	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.8a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
Patients with at least one Grade 1 an 2 AESI, n (%)	0	1 (3.8)	2 (3.3)	3 (2.6)	0.953
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.510		0.777 (0.126, 4.780), 0.785	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.783 (0.134, 4.557), 0.785	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.035, 0.112), 0.308		-0.007 (-0.061, 0.047), 0.792	
Cognitive Effects, n (%)	0	1 (3.8)	2 (3.3)	3 (2.6)	0.953
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.510		0.777 (0.126, 4.780), 0.785	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		0.783 (0.134, 4.557), 0.785	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.035, 0.112), 0.308		-0.007 (-0.061, 0.047), 0.792	
Memory impairment, n (%)	0	0	1 (1.7)	2 (1.7)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		1.044 (0.093, 11.755), 0.972	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		1.043 (0.097, 11.276), 0.972	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.001 (-0.040, 0.041), 0.972	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.8a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
Cognitive Effects (cont.)					
Amnesia, n (%)	0	0	0	1 (0.9)	0.977
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.469	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.009 (-0.008, 0.026), 0.315	
Mood altered, n (%)	0	1 (3.8)	0	0	0.956
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.510		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.035, 0.112), 0.308		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	1 (1.7)	0	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.165	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.017 (-0.049, 0.016), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.8a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.8a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes		No		P-Value [3]
	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	
Cognitive Effects (cont.)					
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.8a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes		No		P-Value [3]
	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	
Cognitive Effects (cont.)					
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental status changes, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.8a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.8a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes		No		P-Value [3]
	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.2.1.8a
Summary of Grade 1 and Grade 2 Adverse Events of Special Interest by Category and Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd1_2-subgrp-a.sas Date: 17:18/05MAY2023

Table 35.3.1.11.3.1.1a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Patients with at least one Grade 3 and Higher AESI, n (%)	0	0	1 (9.1)	0	0.965
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.353	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.091 (-0.261, 0.079), 0.294	
Cognitive Effects, n (%)	0	0	1 (9.1)	0	0.965
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.353	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.091 (-0.261, 0.079), 0.294	
Mental status changes, n (%)	0	0	1 (9.1)	0	0.965
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.353	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.091 (-0.261, 0.079), 0.294	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.1a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.1a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.1a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.1a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.1a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.1a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.1a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<65 Years Placebo (N=60)	<65 Years Avapritinib 25 mg (N=132)	>=65 Years Placebo (N=11)	>=65 Years Avapritinib 25 mg (N=9)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.2a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Patients with at least one Grade 3 and Higher AESI, n (%)	0	0	1 (1.9)	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.172	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.054, 0.017), 0.313	
Cognitive Effects, n (%)	0	0	1 (1.9)	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.172	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.054, 0.017), 0.313	
Mental status changes, n (%)	0	0	1 (1.9)	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.172	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.054, 0.017), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.2a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.2a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.2a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.2a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.2a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.2a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.2a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Male Placebo (N=17)	Male Avapritinib 25 mg (N=41)	Female Placebo (N=54)	Female Avapritinib 25 mg (N=100)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.3a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Patients with at least one Grade 3 and Higher AESI, n (%)	1 (3.0)	0	0	0	0.969
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.175		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.030 (-0.089, 0.028), 0.310		NA (NA, NA), NA	
Cognitive Effects, n (%)	1 (3.0)	0	0	0	0.969
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.175		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.030 (-0.089, 0.028), 0.310		NA (NA, NA), NA	
Mental status changes, n (%)	1 (3.0)	0	0	0	0.969
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.175		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.030 (-0.089, 0.028), 0.310		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.3a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.3a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.3a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.3a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.3a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.3a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.3a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	North America Placebo (N=33)	North America Avapritinib 25 mg (N=60)	Europe Placebo (N=38)	Europe Avapritinib 25 mg (N=81)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Cognitive Effects, n (%)	1 (3.6)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	1 (3.6)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Cognitive Effects, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom		Canada	
	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=8)
Cognitive Effects, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands		Norway	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)
Cognitive Effects, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Cognitive Effects, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden		Switzerland	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=2)
Cognitive Effects, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mental status changes, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Agitation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Amnesia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Mental status changes, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Agitation, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Amnesia, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Cognitive Effects (cont.)	0	0	0	0
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Cognitive Effects (cont.)	0	0	0	0
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	0	0	0	0
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Cognitive Effects (cont.)	0	0	0	0
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=2)	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)
Cognitive Effects (cont.)	0	0	0	0
Cognitive disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Confusional state, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Delirium, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Dementia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Cognitive disorder, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Confusional state, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Delirium, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Dementia, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Cognitive Effects (cont.)	0	0	0	0
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Cognitive Effects (cont.)	0	0	0	0
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	0	0	0	0
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Cognitive Effects (cont.)	0	0	0	0
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden		Switzerland	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=2)
Cognitive Effects (cont.)	0	0	0	0
Disorientation, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Encephalopathy, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hallucination, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Memory impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Disorientation, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Hallucination, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Memory impairment, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden Placebo (N=1)	Sweden Avapritinib 25 mg (N=2)	Switzerland Placebo (N=1)	Switzerland Avapritinib 25 mg (N=2)
Cognitive Effects (cont.)	0	0	0	0
Mental impairment, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Mood altered, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Personality change, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Psychotic disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Mental impairment, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Mood altered, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Personality change, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden		Switzerland	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=2)
Cognitive Effects (cont.)	0	0	0	0
Somnolence, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Speech disorder, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Intracranial Bleeding, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Cerebral haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Cognitive Effects (cont.)	0	0	-
Somnolence, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Speech disorder, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden		Switzerland	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=2)
Intracranial Bleeding (cont.)	0	0	0	0
Cerebral haemorrhage, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Haemorrhage intracranial, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Subdural haematoma, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.9a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Intracranial Bleeding (cont.)	0	0	-
Cerebral haemorrhage, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-country-a.sas Date: 11:52/20JUL2023

Table 35.3.1.11.3.1.4a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Patients with at least one Grade 3 and Higher AESI, n (%)	1 (3.8)	0	0	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.155		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.112, 0.035), 0.308		NA (NA, NA), NA	
Cognitive Effects, n (%)	1 (3.8)	0	0	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.155		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.112, 0.035), 0.308		NA (NA, NA), NA	
Mental status changes, n (%)	1 (3.8)	0	0	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.155		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.038 (-0.112, 0.035), 0.308		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.4a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.4a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.4a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.4a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.4a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.4a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.4a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Moderate Placebo (N=26)	Moderate Avapritinib 25 mg (N=52)	Severe Placebo (N=45)	Severe Avapritinib 25 mg (N=87)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.5a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Patients with at least one Grade 3 and Higher AESI, n (%)	0	0	1 (1.8)	0	0.971
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.154	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.018 (-0.053, 0.017), 0.313	
Cognitive Effects, n (%)	0	0	1 (1.8)	0	0.971
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.154	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.018 (-0.053, 0.017), 0.313	
Mental status changes, n (%)	0	0	1 (1.8)	0	0.971
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.154	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.018 (-0.053, 0.017), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.5a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.5a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.5a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.5a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.5a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.5a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.5a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	<20 ng/mL Placebo (N=15)	<20 ng/mL Avapritinib 25 mg (N=28)	>=20 ng/mL Placebo (N=56)	>=20 ng/mL Avapritinib 25 mg (N=113)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.6a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Patients with at least one Grade 3 and Higher AESI, n (%)	0	0	1 (2.8)	0	0.956
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.164	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.028 (-0.081, 0.026), 0.310	
Cognitive Effects, n (%)	0	0	1 (2.8)	0	0.956
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.164	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.028 (-0.081, 0.026), 0.310	
Mental status changes, n (%)	0	0	1 (2.8)	0	0.956
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.164	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.028 (-0.081, 0.026), 0.310	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.6a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.6a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.6a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.6a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.6a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.6a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.6a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Number of Baseline BSC <4 Placebo (N=35)	 Avapritinib 25 mg (N=72)	Number of Baseline BSC >=4 Placebo (N=36)	 Avapritinib 25 mg (N=69)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.7a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Patients with at least one Grade 3 and Higher AESI, n (%)	0	0	1 (1.6)	0	0.980
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.166	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.016 (-0.046, 0.015), 0.313	
Cognitive Effects, n (%)	0	0	1 (1.6)	0	0.980
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.166	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.016 (-0.046, 0.015), 0.313	
Mental status changes, n (%)	0	0	1 (1.6)	0	0.980
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.166	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.016 (-0.046, 0.015), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.7a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.7a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.7a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.7a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.7a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.7a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.7a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=7)	Yes Avapritinib 25 mg (N=19)	No Placebo (N=64)	No Avapritinib 25 mg (N=122)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.8a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
Patients with at least one Grade 3 and Higher AESI, n (%)	0	0	1 (1.7)	0	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.165	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.017 (-0.049, 0.016), 0.313	
Cognitive Effects, n (%)	0	0	1 (1.7)	0	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.165	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.017 (-0.049, 0.016), 0.313	
Mental status changes, n (%)	0	0	1 (1.7)	0	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.165	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.017 (-0.049, 0.016), 0.313	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.8a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
Cognitive Effects (cont.)					
Agitation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Amnesia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cognitive disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.8a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes		No		P-Value [3]
	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	
Cognitive Effects (cont.)					
Confusional state, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Delirium, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Dementia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.8a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes		No		P-Value [3]
	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	
Cognitive Effects (cont.)					
Disorientation, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Encephalopathy, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hallucination, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.8a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes		No		P-Value [3]
	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	
Cognitive Effects (cont.)					
Memory impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mental impairment, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Mood altered, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.8a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes		No		P-Value [3]
	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	
Cognitive Effects (cont.)					
Personality change, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Psychotic disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Somnolence, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.8a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
Cognitive Effects (cont.)					
Speech disorder, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Intracranial Bleeding, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Cerebral haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.11.3.1.8a
Summary of Grade 3 and Higher Adverse Events of Special Interest by Category and Preferred Term
by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

AESI Category Preferred Term	Yes Placebo (N=11)	Yes Avapritinib 25 mg (N=26)	No Placebo (N=60)	No Avapritinib 25 mg (N=115)	P-Value [3]
Intracranial Bleeding (cont.)					
Cerebral haemorrhage, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Haemorrhage intracranial, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Subdural haematoma, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term/category.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-aesi-grd3-subgrp-a.sas Date: 17:28/05MAY2023

Table 35.3.1.16.1.1.1a
Summary of Oedema CMQ by Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Preferred Term	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [3]
Patients with at least one Oedema CMQ, n (%)	8 (13.3)	30 (22.7)	0	6 (66.7)	0.942
Odds Ratio (95% CIs) [1], P-Value		1.912 (0.818, 4.466), 0.130		NE (NE, NE), 0.001	
Relative Risk (95% CIs) [2], P-Value		1.705 (0.832, 3.494), 0.145		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.094 (-0.018, 0.206), 0.100		0.667 (0.359, 0.975), <0.0001	
Oedema peripheral, n (%)	3 (5.0)	10 (7.6)	0	2 (22.2)	0.949
Odds Ratio (95% CIs) [1], P-Value		1.557 (0.413, 5.877), 0.510		NE (NE, NE), 0.099	
Relative Risk (95% CIs) [2], P-Value		1.515 (0.433, 5.307), 0.516		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.026 (-0.046, 0.097), 0.479		0.222 (-0.049, 0.494), 0.109	
Face oedema, n (%)	1 (1.7)	8 (6.1)	0	2 (22.2)	0.955
Odds Ratio (95% CIs) [1], P-Value		3.806 (0.465, 31.141), 0.182		NE (NE, NE), 0.099	
Relative Risk (95% CIs) [2], P-Value		3.636 (0.465, 28.426), 0.219		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.044 (-0.008, 0.096), 0.098		0.222 (-0.049, 0.494), 0.109	
Periorbital oedema, n (%)	2 (3.3)	6 (4.5)	0	3 (33.3)	0.946
Odds Ratio (95% CIs) [1], P-Value		1.381 (0.271, 7.050), 0.697		NE (NE, NE), 0.038	
Relative Risk (95% CIs) [2], P-Value		1.364 (0.283, 6.561), 0.699		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.012 (-0.046, 0.070), 0.680		0.333 (0.025, 0.641), 0.034	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.1a
Summary of Oedema CMQ by Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Preferred Term	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [3]
Eyelid oedema, n (%)	1 (1.7)	5 (3.8)	0	0	0.995
Odds Ratio (95% CIs) [1], P-Value		2.323 (0.265, 20.326), 0.434		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		2.273 (0.271, 19.034), 0.449		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.021 (-0.025, 0.067), 0.365		NA (NA, NA), NA	
Fluid retention, n (%)	0	2 (1.5)	0	0	0.974
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.338		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.015 (-0.006, 0.036), 0.154		NA (NA, NA), NA	
Swelling of eyelid, n (%)	0	2 (1.5)	0	0	0.974
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.338		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.015 (-0.006, 0.036), 0.154		NA (NA, NA), NA	
Eye oedema, n (%)	1 (1.7)	1 (0.8)	0	0	0.997
Odds Ratio (95% CIs) [1], P-Value		0.450 (0.028, 7.324), 0.565		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.455 (0.029, 7.146), 0.575		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.009 (-0.045, 0.027), 0.617		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.1a
Summary of Oedema CMQ by Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Preferred Term	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [3]
Generalised oedema, n (%)	0	1 (0.8)	0	0	0.982
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.499		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.008 (-0.007, 0.022), 0.315		NA (NA, NA), NA	
Oedema, n (%)	0	1 (0.8)	0	0	0.982
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.499		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.008 (-0.007, 0.022), 0.315		NA (NA, NA), NA	
Eye swelling, n (%)	1 (1.7)	0	0	0	0.981
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.137		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.017 (-0.049, 0.016), 0.313		NA (NA, NA), NA	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.1a
Summary of Oedema CMQ by Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Preferred Term	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.1a
Summary of Oedema CMQ by Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Preferred Term	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.1a
Summary of Oedema CMQ by Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Preferred Term	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.2a
Summary of Oedema CMQ by Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

	Male		Female		
Preferred Term	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [3]
Patients with at least one Oedema CMQ, n (%)	1 (5.9)	9 (22.0)	7 (13.0)	27 (27.0)	0.618
Odds Ratio (95% CIs) [1], P-Value		4.500 (0.523, 38.685), 0.140		2.483 (1.001, 6.160), 0.045	
Relative Risk (95% CIs) [2], P-Value		3.732 (0.512, 27.221), 0.194		2.083 (0.972, 4.465), 0.059	
Risk Difference (95% CIs) [2], P-Value		0.161 (-0.008, 0.330), 0.062		0.140 (0.015, 0.265), 0.028	
Oedema peripheral, n (%)	1 (5.9)	4 (9.8)	2 (3.7)	8 (8.0)	0.850
Odds Ratio (95% CIs) [1], P-Value		1.730 (0.179, 16.716), 0.632		2.261 (0.463, 11.046), 0.302	
Relative Risk (95% CIs) [2], P-Value		1.659 (0.200, 13.778), 0.640		2.160 (0.475, 9.814), 0.319	
Risk Difference (95% CIs) [2], P-Value		0.039 (-0.105, 0.183), 0.598		0.043 (-0.030, 0.116), 0.250	
Face oedema, n (%)	0	2 (4.9)	1 (1.9)	8 (8.0)	0.958
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.354		4.609 (0.561, 37.868), 0.121	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		4.320 (0.555, 33.636), 0.162	
Risk Difference (95% CIs) [2], P-Value		0.049 (-0.017, 0.115), 0.147		0.061 (-0.003, 0.126), 0.060	
Periorbital oedema, n (%)	0	3 (7.3)	2 (3.7)	6 (6.0)	0.951
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.252		1.660 (0.323, 8.519), 0.540	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.620 (0.338, 7.753), 0.546	
Risk Difference (95% CIs) [2], P-Value		0.073 (-0.007, 0.153), 0.072		0.023 (-0.046, 0.092), 0.512	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.2a
Summary of Oedema CMQ by Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

	Male		Female		
Preferred Term	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [3]
Eyelid oedema, n (%)	0	2 (4.9)	1 (1.9)	3 (3.0)	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.354		1.639 (0.166, 16.151), 0.669	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.620 (0.173, 15.200), 0.673	
Risk Difference (95% CIs) [2], P-Value		0.049 (-0.017, 0.115), 0.147		0.011 (-0.038, 0.061), 0.647	
Fluid retention, n (%)	0	0	0	2 (2.0)	0.961
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.296	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.020 (-0.007, 0.047), 0.153	
Swelling of eyelid, n (%)	0	0	0	2 (2.0)	0.961
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.296	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.020 (-0.007, 0.047), 0.153	
Eye oedema, n (%)	0	0	1 (1.9)	1 (1.0)	0.997
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.535 (0.033, 8.732), 0.656	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.540 (0.034, 8.464), 0.661	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.009 (-0.049, 0.032), 0.683	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.2a
Summary of Oedema CMQ by Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

	Male		Female		
Preferred Term	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [3]
Generalised oedema, n (%)	0	0	0	1 (1.0)	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.461	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.010, 0.030), 0.315	
Oedema, n (%)	0	0	0	1 (1.0)	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.461	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.010, 0.030), 0.315	
Eye swelling, n (%)	0	0	1 (1.9)	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.172	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.054, 0.017), 0.313	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.2a
Summary of Oedema CMQ by Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

	Male		Female		
Preferred Term	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.2a
Summary of Oedema CMQ by Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

	Male		Female		
Preferred Term	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.2a
Summary of Oedema CMQ by Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

	Male		Female		
Preferred Term	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.3a
Summary of Oedema CMQ by Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Preferred Term	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [3]
Patients with at least one Oedema CMQ, n (%)	5 (15.2)	15 (25.0)	3 (7.9)	21 (25.9)	0.366
Odds Ratio (95% CIs) [1], P-Value		1.867 (0.611, 5.702), 0.269		4.083 (1.136, 14.679), 0.022	
Relative Risk (95% CIs) [2], P-Value		1.650 (0.658, 4.135), 0.285		3.284 (1.043, 10.337), 0.042	
Risk Difference (95% CIs) [2], P-Value		0.098 (-0.066, 0.263), 0.240		0.180 (0.052, 0.309), 0.006	
Oedema peripheral, n (%)	2 (6.1)	6 (10.0)	1 (2.6)	6 (7.4)	0.696
Odds Ratio (95% CIs) [1], P-Value		1.722 (0.327, 9.059), 0.517		2.960 (0.344, 25.495), 0.302	
Relative Risk (95% CIs) [2], P-Value		1.650 (0.353, 7.719), 0.525		2.815 (0.351, 22.568), 0.330	
Risk Difference (95% CIs) [2], P-Value		0.039 (-0.072, 0.151), 0.488		0.048 (-0.029, 0.124), 0.221	
Face oedema, n (%)	1 (3.0)	5 (8.3)	0	5 (6.2)	0.954
Odds Ratio (95% CIs) [1], P-Value		2.909 (0.325, 26.014), 0.319		NE (NE, NE), 0.118	
Relative Risk (95% CIs) [2], P-Value		2.750 (0.335, 22.560), 0.346		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.038, 0.144), 0.254		0.062 (0.009, 0.114), 0.021	
Periorbital oedema, n (%)	1 (3.0)	5 (8.3)	1 (2.6)	4 (4.9)	0.795
Odds Ratio (95% CIs) [1], P-Value		2.909 (0.325, 26.014), 0.319		1.922 (0.207, 17.806), 0.559	
Relative Risk (95% CIs) [2], P-Value		2.750 (0.335, 22.560), 0.346		1.877 (0.217, 16.225), 0.567	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.038, 0.144), 0.254		0.023 (-0.046, 0.092), 0.515	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.3a
Summary of Oedema CMQ by Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Preferred Term	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [3]
Eyelid oedema, n (%)	0	0	1 (2.6)	5 (6.2)	0.996
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		2.434 (0.274, 21.592), 0.410	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		2.346 (0.284, 19.390), 0.429	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.035 (-0.038, 0.108), 0.342	
Fluid retention, n (%)	0	1 (1.7)	0	1 (1.2)	0.999
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.456		NE (NE, NE), 0.492	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.017 (-0.016, 0.049), 0.313		0.012 (-0.012, 0.036), 0.314	
Swelling of eyelid, n (%)	0	2 (3.3)	0	0	0.966
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.289		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.033 (-0.012, 0.079), 0.150		NA (NA, NA), NA	
Eye oedema, n (%)	1 (3.0)	0	0	1 (1.2)	0.919
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.175		NE (NE, NE), 0.492	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.030 (-0.089, 0.028), 0.310		0.012 (-0.012, 0.036), 0.314	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.3a
Summary of Oedema CMQ by Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Preferred Term	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [3]
Generalised oedema, n (%)	0	0	0	1 (1.2)	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.492	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.012 (-0.012, 0.036), 0.314	
Oedema, n (%)	0	0	0	1 (1.2)	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.492	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.012 (-0.012, 0.036), 0.314	
Eye swelling, n (%)	1 (3.0)	0	0	0	0.969
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.175		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.030 (-0.089, 0.028), 0.310		NA (NA, NA), NA	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.3a
Summary of Oedema CMQ by Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Preferred Term	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.3a
Summary of Oedema CMQ by Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Preferred Term	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.3a
Summary of Oedema CMQ by Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Preferred Term	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Patients with at least one Oedema CMQ, n (%)	4 (14.3)	11 (21.2)	1 (6.7)	4 (21.1)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	2 (7.1)	5 (9.6)	0	1 (5.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	2 (3.8)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Periorbital oedema, n (%)	1 (3.6)	4 (7.7)	0	1 (5.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France		Spain	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=3)	Avapritinib 25 mg (N=14)
Patients with at least one Oedema CMQ, n (%)	0	2 (18.2)	0	7 (50.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	0	0	0	2 (14.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	1 (9.1)	0	2 (14.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Periorbital oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Patients with at least one Oedema CMQ, n (%)	0	2 (18.2)	1 (20.0)	4 (50.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	0	1 (9.1)	0	1 (12.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	1 (9.1)	1 (20.0)	3 (37.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Periorbital oedema, n (%)	0	1 (9.1)	0	1 (12.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Patients with at least one Oedema CMQ, n (%)	0	1 (11.1)	0	2 (40.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	0	0	0	1 (20.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Periorbital oedema, n (%)	0	0	0	1 (20.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium		Italy	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=0)	Avapritinib 25 mg (N=4)
Patients with at least one Oedema CMQ, n (%)	0	1 (33.3)	0	1 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	0	1 (33.3)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	1 (33.3)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Periorbital oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden		Switzerland	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=2)
Patients with at least one Oedema CMQ, n (%)	1 (100.0)	0	1 (100.0)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	1 (100.0)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Periorbital oedema, n (%)	0	0	1 (100.0)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Patients with at least one Oedema CMQ, n (%)	0	1 (100.0)	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Oedema peripheral, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Face oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Periorbital oedema, n (%)	0	1 (100.0)	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Eyelid oedema, n (%)	0	0	1 (6.7)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Fluid retention, n (%)	0	1 (1.9)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling of eyelid, n (%)	0	2 (3.8)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye oedema, n (%)	1 (3.6)	0	0	1 (5.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France		Spain	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=3)	Avapritinib 25 mg (N=14)
Eyelid oedema, n (%)	0	1 (9.1)	0	4 (28.6)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Fluid retention, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling of eyelid, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Eyelid oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Fluid retention, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling of eyelid, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands		Norway	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)
Eyelid oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Fluid retention, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling of eyelid, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Eyelid oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Fluid retention, n (%)	0	0	0	1 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling of eyelid, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden		Switzerland	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=2)
Eyelid oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Fluid retention, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling of eyelid, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Eyelid oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Fluid retention, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Swelling of eyelid, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Eye oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Generalised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema, n (%)	0	0	0	1 (5.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye swelling, n (%)	1 (3.6)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Abdominal wall oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France		Spain	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=3)	Avapritinib 25 mg (N=14)
Generalised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Abdominal wall oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Generalised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Abdominal wall oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Generalised oedema, n (%)	0	1 (11.1)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Abdominal wall oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium		Italy	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=0)	Avapritinib 25 mg (N=4)
Generalised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Abdominal wall oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden		Switzerland	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=2)
Generalised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Abdominal wall oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Generalised oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Eye swelling, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Abdominal wall oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Capillary leak syndrome, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Extensive interdialytic weight gain, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Gravitational oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hydraemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Capillary leak syndrome, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Extensive interdialytic weight gain, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Gravitational oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hydraemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom		Canada	
	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=8)
Capillary leak syndrome, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Extensive interdialytic weight gain, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Gravitational oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hydraemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Capillary leak syndrome, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Extensive interdialytic weight gain, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Gravitational oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hydraemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium Placebo (N=1)	Belgium Avapritinib 25 mg (N=3)	Italy Placebo (N=0)	Italy Avapritinib 25 mg (N=4)
Capillary leak syndrome, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Extensive interdialytic weight gain, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Gravitational oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hydraemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden		Switzerland	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=2)
Capillary leak syndrome, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Extensive interdialytic weight gain, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Gravitational oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hydraemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Hypervolaemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Localised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Non-pitting oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema blister, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France		Spain	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=3)	Avapritinib 25 mg (N=14)
Hypervolaemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Localised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Non-pitting oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema blister, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Hypervolaemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Localised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Non-pitting oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema blister, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Hypervolaemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Localised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Non-pitting oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema blister, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium		Italy	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=0)	Avapritinib 25 mg (N=4)
Hypervolaemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Localised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Non-pitting oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema blister, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden		Switzerland	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=2)
Hypervolaemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Localised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Non-pitting oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema blister, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Hypervolaemia, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Periorbital swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Stoma site oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling face, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Visceral oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Periorbital swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Stoma site oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling face, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Visceral oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Periorbital swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Stoma site oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling face, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Visceral oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands		Norway	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)
Periorbital swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Stoma site oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling face, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Visceral oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium		Italy	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=0)	Avapritinib 25 mg (N=4)
Periorbital swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Stoma site oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling face, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Visceral oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden		Switzerland	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=2)
Periorbital swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Stoma site oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling face, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Visceral oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.9a
Summary of Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Periorbital swelling, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Swelling face, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.1.1.4a
Summary of Oedema CMQ by Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Preferred Term	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [3]
Patients with at least one Oedema CMQ, n (%)	2 (7.7)	10 (19.2)	6 (13.3)	26 (29.9)	0.974
Odds Ratio (95% CIs) [1], P-Value		2.857 (0.577, 14.136), 0.183		2.770 (1.046, 7.341), 0.035	
Relative Risk (95% CIs) [2], P-Value		2.500 (0.590, 10.587), 0.213		2.241 (0.996, 5.046), 0.051	
Risk Difference (95% CIs) [2], P-Value		0.115 (-0.033, 0.264), 0.127		0.166 (0.027, 0.304), 0.019	
Oedema peripheral, n (%)	1 (3.8)	5 (9.6)	2 (4.4)	7 (8.0)	0.804
Odds Ratio (95% CIs) [1], P-Value		2.660 (0.294, 24.031), 0.367		1.881 (0.374, 9.455), 0.436	
Relative Risk (95% CIs) [2], P-Value		2.500 (0.308, 20.309), 0.391		1.810 (0.392, 8.358), 0.447	
Risk Difference (95% CIs) [2], P-Value		0.058 (-0.051, 0.167), 0.300		0.036 (-0.047, 0.119), 0.395	
Face oedema, n (%)	0	4 (7.7)	1 (2.2)	6 (6.9)	0.961
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.147		3.259 (0.380, 27.941), 0.256	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		3.103 (0.385, 24.996), 0.287	
Risk Difference (95% CIs) [2], P-Value		0.077 (0.004, 0.149), 0.037		0.047 (-0.022, 0.115), 0.181	
Periorbital oedema, n (%)	1 (3.8)	1 (1.9)	1 (2.2)	8 (9.2)	0.219
Odds Ratio (95% CIs) [1], P-Value		0.490 (0.029, 8.165), 0.612		4.456 (0.539, 36.799), 0.132	
Relative Risk (95% CIs) [2], P-Value		0.500 (0.033, 7.678), 0.619		4.138 (0.534, 32.062), 0.174	
Risk Difference (95% CIs) [2], P-Value		-0.019 (-0.102, 0.064), 0.649		0.070 (-0.005, 0.144), 0.066	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.4a
Summary of Oedema CMQ by Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Preferred Term	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [3]
Eyelid oedema, n (%)	0	1 (1.9)	1 (2.2)	4 (4.6)	0.959
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.477		2.120 (0.230, 19.555), 0.498	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.069 (0.238, 17.968), 0.510	
Risk Difference (95% CIs) [2], P-Value		0.019 (-0.018, 0.057), 0.313		0.024 (-0.038, 0.085), 0.450	
Fluid retention, n (%)	0	0	0	2 (2.3)	0.970
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.305	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.023 (-0.009, 0.054), 0.153	
Swelling of eyelid, n (%)	0	0	0	2 (2.3)	0.970
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.305	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.023 (-0.009, 0.054), 0.153	
Eye oedema, n (%)	0	1 (1.9)	1 (2.2)	0	0.924
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.477		NE (NE, NE), 0.163	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.019 (-0.018, 0.057), 0.313		-0.022 (-0.065, 0.021), 0.312	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.4a
Summary of Oedema CMQ by Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Preferred Term	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [3]
Generalised oedema, n (%)	0	0	0	1 (1.1)	0.968
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.470	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.011 (-0.011, 0.034), 0.315	
Oedema, n (%)	0	0	0	1 (1.1)	0.968
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.470	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.011 (-0.011, 0.034), 0.315	
Eye swelling, n (%)	0	0	1 (2.2)	0	0.962
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.163	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.022 (-0.065, 0.021), 0.312	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.4a
Summary of Oedema CMQ by Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Preferred Term	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.4a
Summary of Oedema CMQ by Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Preferred Term	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.4a
Summary of Oedema CMQ by Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Preferred Term	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.5a
Summary of Oedema CMQ by Preferred Term by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Preferred Term	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [3]
Patients with at least one Oedema CMQ, n (%)	2 (13.3)	6 (21.4)	6 (10.7)	30 (26.5)	0.600
Odds Ratio (95% CIs) [1], P-Value		1.773 (0.311, 10.110), 0.516		3.012 (1.172, 7.743), 0.018	
Relative Risk (95% CIs) [2], P-Value		1.607 (0.369, 7.006), 0.528		2.478 (1.096, 5.603), 0.029	
Risk Difference (95% CIs) [2], P-Value		0.081 (-0.149, 0.311), 0.489		0.158 (0.043, 0.273), 0.007	
Oedema peripheral, n (%)	1 (6.7)	2 (7.1)	2 (3.6)	10 (8.8)	0.552
Odds Ratio (95% CIs) [1], P-Value		1.077 (0.090, 12.948), 0.953		2.621 (0.554, 12.394), 0.209	
Relative Risk (95% CIs) [2], P-Value		1.071 (0.106, 10.871), 0.953		2.478 (0.562, 10.929), 0.231	
Risk Difference (95% CIs) [2], P-Value		0.005 (-0.153, 0.163), 0.953		0.053 (-0.019, 0.124), 0.148	
Face oedema, n (%)	0	3 (10.7)	1 (1.8)	7 (6.2)	0.970
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.189		3.632 (0.436, 30.273), 0.204	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		3.469 (0.437, 27.510), 0.239	
Risk Difference (95% CIs) [2], P-Value		0.107 (-0.007, 0.222), 0.067		0.044 (-0.012, 0.100), 0.125	
Periorbital oedema, n (%)	0	1 (3.6)	2 (3.6)	8 (7.1)	0.972
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.459		2.057 (0.422, 10.026), 0.363	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.982 (0.435, 9.028), 0.376	
Risk Difference (95% CIs) [2], P-Value		0.036 (-0.033, 0.104), 0.309		0.035 (-0.033, 0.103), 0.311	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.5a
Summary of Oedema CMQ by Preferred Term by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Preferred Term	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [3]
Eyelid oedema, n (%)	0	0	1 (1.8)	5 (4.4)	0.997
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		2.546 (0.290, 22.333), 0.383	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		2.478 (0.297, 20.706), 0.402	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.026 (-0.025, 0.078), 0.314	
Fluid retention, n (%)	0	1 (3.6)	0	1 (0.9)	0.997
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.459		NE (NE, NE), 0.480	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.036 (-0.033, 0.104), 0.309		0.009 (-0.008, 0.026), 0.315	
Swelling of eyelid, n (%)	0	0	0	2 (1.8)	0.976
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.317	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.018 (-0.007, 0.042), 0.154	
Eye oedema, n (%)	0	0	1 (1.8)	1 (0.9)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.491 (0.030, 7.999), 0.610	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.496 (0.032, 7.777), 0.617	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.009 (-0.048, 0.030), 0.649	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.5a
Summary of Oedema CMQ by Preferred Term by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Preferred Term	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [3]
Generalised oedema, n (%)	0	0	0	1 (0.9)	0.975
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.480	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.009 (-0.008, 0.026), 0.315	
Oedema, n (%)	0	1 (3.6)	0	0	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.459		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.036 (-0.033, 0.104), 0.309		NA (NA, NA), NA	
Eye swelling, n (%)	1 (6.7)	0	0	0	0.972
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.167		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.067 (-0.193, 0.060), 0.301		NA (NA, NA), NA	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.5a
Summary of Oedema CMQ by Preferred Term by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Preferred Term	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.5a
Summary of Oedema CMQ by Preferred Term by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Preferred Term	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.5a
Summary of Oedema CMQ by Preferred Term by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Preferred Term	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.6a
Summary of Oedema CMQ by Preferred Term by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Preferred Term	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [3]
Patients with at least one Oedema CMQ, n (%)	2 (5.7)	17 (23.6)	6 (16.7)	19 (27.5)	0.293
Odds Ratio (95% CIs) [1], P-Value		5.100 (1.107, 23.492), 0.023		1.900 (0.683, 5.287), 0.215	
Relative Risk (95% CIs) [2], P-Value		4.132 (1.010, 16.897), 0.048		1.652 (0.724, 3.769), 0.233	
Risk Difference (95% CIs) [2], P-Value		0.179 (0.054, 0.304), 0.005		0.109 (-0.052, 0.270), 0.186	
Oedema peripheral, n (%)	1 (2.9)	5 (6.9)	2 (5.6)	7 (10.1)	0.841
Odds Ratio (95% CIs) [1], P-Value		2.537 (0.285, 22.589), 0.389		1.919 (0.377, 9.759), 0.425	
Relative Risk (95% CIs) [2], P-Value		2.431 (0.295, 20.022), 0.409		1.826 (0.400, 8.340), 0.437	
Risk Difference (95% CIs) [2], P-Value		0.041 (-0.040, 0.121), 0.320		0.046 (-0.057, 0.149), 0.384	
Face oedema, n (%)	0	5 (6.9)	1 (2.8)	5 (7.2)	0.955
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.110		2.734 (0.307, 24.340), 0.349	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.609 (0.317, 21.493), 0.373	
Risk Difference (95% CIs) [2], P-Value		0.069 (0.011, 0.128), 0.020		0.045 (-0.037, 0.126), 0.282	
Periorbital oedema, n (%)	0	2 (2.8)	2 (5.6)	7 (10.1)	0.958
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.320		1.919 (0.377, 9.759), 0.425	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.826 (0.400, 8.340), 0.437	
Risk Difference (95% CIs) [2], P-Value		0.028 (-0.010, 0.066), 0.151		0.046 (-0.057, 0.149), 0.384	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.6a
Summary of Oedema CMQ by Preferred Term by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Preferred Term	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [3]
Eyelid oedema, n (%)	1 (2.9)	1 (1.4)	0	4 (5.8)	0.938
Odds Ratio (95% CIs) [1], P-Value		0.479 (0.029, 7.889), 0.599		NE (NE, NE), 0.141	
Relative Risk (95% CIs) [2], P-Value		0.486 (0.031, 7.545), 0.606		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.015 (-0.076, 0.047), 0.640		0.058 (0.003, 0.113), 0.039	
Fluid retention, n (%)	0	2 (2.8)	0	0	0.952
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.320		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.028 (-0.010, 0.066), 0.151		NA (NA, NA), NA	
Swelling of eyelid, n (%)	0	1 (1.4)	0	1 (1.4)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.484		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.014 (-0.013, 0.041), 0.314		0.014 (-0.014, 0.043), 0.314	
Eye oedema, n (%)	0	1 (1.4)	1 (2.8)	0	0.919
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.484		NE (NE, NE), 0.164	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.014 (-0.013, 0.041), 0.314		-0.028 (-0.081, 0.026), 0.310	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.6a
Summary of Oedema CMQ by Preferred Term by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Preferred Term	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [3]
Generalised oedema, n (%)	0	1 (1.4)	0	0	0.966
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.484		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.014 (-0.013, 0.041), 0.314		NA (NA, NA), NA	
Oedema, n (%)	0	1 (1.4)	0	0	0.966
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.484		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.014 (-0.013, 0.041), 0.314		NA (NA, NA), NA	
Eye swelling, n (%)	0	0	1 (2.8)	0	0.956
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.164	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.028 (-0.081, 0.026), 0.310	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.6a
Summary of Oedema CMQ by Preferred Term by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Preferred Term	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.6a
Summary of Oedema CMQ by Preferred Term by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Preferred Term	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.6a
Summary of Oedema CMQ by Preferred Term by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Preferred Term	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.7a
Summary of Oedema CMQ by Preferred Term by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [3]
Patients with at least one Oedema CMQ, n (%)	0	5 (26.3)	8 (12.5)	31 (25.4)	0.960
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.131		2.385 (1.024, 5.554), 0.040	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.033 (0.993, 4.159), 0.052	
Risk Difference (95% CIs) [2], P-Value		0.263 (0.065, 0.461), 0.009		0.129 (0.017, 0.241), 0.024	
Oedema peripheral, n (%)	0	2 (10.5)	3 (4.7)	10 (8.2)	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.372		1.815 (0.481, 6.846), 0.373	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.749 (0.499, 6.129), 0.383	
Risk Difference (95% CIs) [2], P-Value		0.105 (-0.033, 0.243), 0.135		0.035 (-0.036, 0.106), 0.333	
Face oedema, n (%)	0	2 (10.5)	1 (1.6)	8 (6.6)	0.956
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.372		4.421 (0.541, 36.157), 0.132	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		4.197 (0.537, 32.820), 0.172	
Risk Difference (95% CIs) [2], P-Value		0.105 (-0.033, 0.243), 0.135		0.050 (-0.003, 0.103), 0.067	
Periorbital oedema, n (%)	0	1 (5.3)	2 (3.1)	8 (6.6)	0.956
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.536		2.175 (0.448, 10.562), 0.324	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.098 (0.459, 9.591), 0.339	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		0.034 (-0.027, 0.096), 0.272	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.7a
Summary of Oedema CMQ by Preferred Term by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [3]
Eyelid oedema, n (%)	0	0	1 (1.6)	5 (4.1)	0.995
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		2.692 (0.308, 23.551), 0.352	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		2.623 (0.313, 21.975), 0.374	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.025 (-0.021, 0.072), 0.285	
Fluid retention, n (%)	0	0	0	2 (1.6)	0.974
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.303	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.016 (-0.006, 0.039), 0.154	
Swelling of eyelid, n (%)	0	1 (5.3)	0	1 (0.8)	0.997
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.536		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		0.008 (-0.008, 0.024), 0.315	
Eye oedema, n (%)	0	0	1 (1.6)	1 (0.8)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.521 (0.032, 8.464), 0.641	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.525 (0.033, 8.249), 0.646	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.007 (-0.042, 0.027), 0.672	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.7a
Summary of Oedema CMQ by Preferred Term by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [3]
Generalised oedema, n (%)	0	0	0	1 (0.8)	0.981
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.008 (-0.008, 0.024), 0.315	
Oedema, n (%)	0	1 (5.3)	0	0	0.959
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.536		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		NA (NA, NA), NA	
Eye swelling, n (%)	0	0	1 (1.6)	0	0.980
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.166	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.016 (-0.046, 0.015), 0.313	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.7a
Summary of Oedema CMQ by Preferred Term by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.7a
Summary of Oedema CMQ by Preferred Term by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.7a
Summary of Oedema CMQ by Preferred Term by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.8a
Summary of Oedema CMQ by Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [3]
Patients with at least one Oedema CMQ, n (%)	2 (18.2)	6 (23.1)	6 (10.0)	30 (26.1)	0.406
Odds Ratio (95% CIs) [1], P-Value		1.350 (0.227, 8.031), 0.741		3.176 (1.240, 8.136), 0.012	
Relative Risk (95% CIs) [2], P-Value		1.269 (0.302, 5.339), 0.745		2.609 (1.150, 5.917), 0.022	
Risk Difference (95% CIs) [2], P-Value		0.049 (-0.231, 0.329), 0.731		0.161 (0.050, 0.271), 0.004	
Oedema peripheral, n (%)	0	2 (7.7)	3 (5.0)	10 (8.7)	0.955
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.344		1.810 (0.479, 6.841), 0.376	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.739 (0.497, 6.082), 0.386	
Risk Difference (95% CIs) [2], P-Value		0.077 (-0.026, 0.179), 0.141		0.037 (-0.038, 0.112), 0.337	
Face oedema, n (%)	0	4 (15.4)	1 (1.7)	6 (5.2)	0.960
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.168		3.248 (0.382, 27.620), 0.255	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		3.130 (0.386, 25.407), 0.285	
Risk Difference (95% CIs) [2], P-Value		0.154 (0.015, 0.293), 0.030		0.036 (-0.016, 0.087), 0.181	
Periorbital oedema, n (%)	0	1 (3.8)	2 (3.3)	8 (7.0)	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.510		2.168 (0.446, 10.549), 0.327	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.087 (0.457, 9.520), 0.342	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.035, 0.112), 0.308		0.036 (-0.029, 0.101), 0.275	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.8a
Summary of Oedema CMQ by Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [3]
Eyelid oedema, n (%)	0	0	1 (1.7)	5 (4.3)	0.996
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		2.682 (0.306, 23.493), 0.355	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		2.609 (0.312, 21.825), 0.376	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.027 (-0.023, 0.076), 0.287	
Fluid retention, n (%)	0	1 (3.8)	0	1 (0.9)	0.998
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.510		NE (NE, NE), 0.469	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.035, 0.112), 0.308		0.009 (-0.008, 0.026), 0.315	
Swelling of eyelid, n (%)	0	0	0	2 (1.7)	0.968
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.304	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.017 (-0.007, 0.041), 0.154	
Eye oedema, n (%)	1 (9.1)	0	0	1 (0.9)	0.900
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.119		NE (NE, NE), 0.469	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.091 (-0.261, 0.079), 0.294		0.009 (-0.008, 0.026), 0.315	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.8a
Summary of Oedema CMQ by Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [3]
Generalised oedema, n (%)	0	0	0	1 (0.9)	0.977
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.469	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.009 (-0.008, 0.026), 0.315	
Oedema, n (%)	0	0	0	1 (0.9)	0.977
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.469	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.009 (-0.008, 0.026), 0.315	
Eye swelling, n (%)	1 (9.1)	0	0	0	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.119		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.091 (-0.261, 0.079), 0.294		NA (NA, NA), NA	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.8a
Summary of Oedema CMQ by Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.8a
Summary of Oedema CMQ by Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.1.1.8a
Summary of Oedema CMQ by Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-subgrp-a.sas Date: 17:16/05MAY2023

Table 35.3.1.16.3.1.1a
Summary of Serious Oedema CMQ by Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sae-cmq-subgrp-a.sas Date: 17:19/05MAY2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.16.3.1.2a
Summary of Serious Oedema CMQ by Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sae-cmq-subgrp-a.sas Date: 17:19/05MAY2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.16.3.1.3a
Summary of Serious Oedema CMQ by Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sae-cmq-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.16.3.1.9a
Summary of Serious Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sae-cmq-country-a.sas Date: 11:52/20JUL2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.16.3.1.4a
Summary of Serious Oedema CMQ by Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sae-cmq-subgrp-a.sas Date: 17:19/05MAY2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.16.3.1.5a
Summary of Serious Oedema CMQ by Preferred Term by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sae-cmq-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.16.3.1.6a
Summary of Serious Oedema CMQ by Preferred Term by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sae-cmq-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.16.3.1.7a
Summary of Serious Oedema CMQ by Preferred Term by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sae-cmq-subgrp-a.sas Date: 17:19/05MAY2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.16.3.1.8a
Summary of Serious Oedema CMQ by Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-sae-cmq-subgrp-a.sas Date: 17:19/05MAY2023

Table 35.3.1.16.2.1.1.1a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Preferred Term	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [3]
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	8 (13.3)	30 (22.7)	0	6 (66.7)	0.942
Odds Ratio (95% CIs) [1], P-Value		1.912 (0.818, 4.466), 0.130		NE (NE, NE), 0.001	
Relative Risk (95% CIs) [2], P-Value		1.705 (0.832, 3.494), 0.145		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.094 (-0.018, 0.206), 0.100		0.667 (0.359, 0.975), <0.0001	
Oedema peripheral, n (%)	3 (5.0)	10 (7.6)	0	2 (22.2)	0.949
Odds Ratio (95% CIs) [1], P-Value		1.557 (0.413, 5.877), 0.510		NE (NE, NE), 0.099	
Relative Risk (95% CIs) [2], P-Value		1.515 (0.433, 5.307), 0.516		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.026 (-0.046, 0.097), 0.479		0.222 (-0.049, 0.494), 0.109	
Face oedema, n (%)	1 (1.7)	8 (6.1)	0	2 (22.2)	0.955
Odds Ratio (95% CIs) [1], P-Value		3.806 (0.465, 31.141), 0.182		NE (NE, NE), 0.099	
Relative Risk (95% CIs) [2], P-Value		3.636 (0.465, 28.426), 0.219		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.044 (-0.008, 0.096), 0.098		0.222 (-0.049, 0.494), 0.109	
Periorbital oedema, n (%)	2 (3.3)	6 (4.5)	0	3 (33.3)	0.946
Odds Ratio (95% CIs) [1], P-Value		1.381 (0.271, 7.050), 0.697		NE (NE, NE), 0.038	
Relative Risk (95% CIs) [2], P-Value		1.364 (0.283, 6.561), 0.699		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.012 (-0.046, 0.070), 0.680		0.333 (0.025, 0.641), 0.034	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.1a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Preferred Term	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [3]
Eyelid oedema, n (%)	1 (1.7)	5 (3.8)	0	0	0.995
Odds Ratio (95% CIs) [1], P-Value		2.323 (0.265, 20.326), 0.434		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		2.273 (0.271, 19.034), 0.449		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.021 (-0.025, 0.067), 0.365		NA (NA, NA), NA	
Fluid retention, n (%)	0	2 (1.5)	0	0	0.974
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.338		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.015 (-0.006, 0.036), 0.154		NA (NA, NA), NA	
Swelling of eyelid, n (%)	0	2 (1.5)	0	0	0.974
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.338		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.015 (-0.006, 0.036), 0.154		NA (NA, NA), NA	
Eye oedema, n (%)	1 (1.7)	1 (0.8)	0	0	0.997
Odds Ratio (95% CIs) [1], P-Value		0.450 (0.028, 7.324), 0.565		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		0.455 (0.029, 7.146), 0.575		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.009 (-0.045, 0.027), 0.617		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.1a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Preferred Term	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [3]
Generalised oedema, n (%)	0	1 (0.8)	0	0	0.982
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.499		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.008 (-0.007, 0.022), 0.315		NA (NA, NA), NA	
Oedema, n (%)	0	1 (0.8)	0	0	0.982
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.499		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.008 (-0.007, 0.022), 0.315		NA (NA, NA), NA	
Eye swelling, n (%)	1 (1.7)	0	0	0	0.981
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.137		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.017 (-0.049, 0.016), 0.313		NA (NA, NA), NA	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.1a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Preferred Term	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.1a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Preferred Term	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.1a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
Preferred Term	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.2a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

	Male		Female		
Preferred Term	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [3]
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	1 (5.9)	9 (22.0)	7 (13.0)	27 (27.0)	0.618
Odds Ratio (95% CIs) [1], P-Value		4.500 (0.523, 38.685), 0.140		2.483 (1.001, 6.160), 0.045	
Relative Risk (95% CIs) [2], P-Value		3.732 (0.512, 27.221), 0.194		2.083 (0.972, 4.465), 0.059	
Risk Difference (95% CIs) [2], P-Value		0.161 (-0.008, 0.330), 0.062		0.140 (0.015, 0.265), 0.028	
Oedema peripheral, n (%)	1 (5.9)	4 (9.8)	2 (3.7)	8 (8.0)	0.850
Odds Ratio (95% CIs) [1], P-Value		1.730 (0.179, 16.716), 0.632		2.261 (0.463, 11.046), 0.302	
Relative Risk (95% CIs) [2], P-Value		1.659 (0.200, 13.778), 0.640		2.160 (0.475, 9.814), 0.319	
Risk Difference (95% CIs) [2], P-Value		0.039 (-0.105, 0.183), 0.598		0.043 (-0.030, 0.116), 0.250	
Face oedema, n (%)	0	2 (4.9)	1 (1.9)	8 (8.0)	0.958
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.354		4.609 (0.561, 37.868), 0.121	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		4.320 (0.555, 33.636), 0.162	
Risk Difference (95% CIs) [2], P-Value		0.049 (-0.017, 0.115), 0.147		0.061 (-0.003, 0.126), 0.060	
Periorbital oedema, n (%)	0	3 (7.3)	2 (3.7)	6 (6.0)	0.951
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.252		1.660 (0.323, 8.519), 0.540	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.620 (0.338, 7.753), 0.546	
Risk Difference (95% CIs) [2], P-Value		0.073 (-0.007, 0.153), 0.072		0.023 (-0.046, 0.092), 0.512	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.2a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

	Male		Female		
Preferred Term	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [3]
Eyelid oedema, n (%)	0	2 (4.9)	1 (1.9)	3 (3.0)	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.354		1.639 (0.166, 16.151), 0.669	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.620 (0.173, 15.200), 0.673	
Risk Difference (95% CIs) [2], P-Value		0.049 (-0.017, 0.115), 0.147		0.011 (-0.038, 0.061), 0.647	
Fluid retention, n (%)	0	0	0	2 (2.0)	0.961
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.296	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.020 (-0.007, 0.047), 0.153	
Swelling of eyelid, n (%)	0	0	0	2 (2.0)	0.961
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.296	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.020 (-0.007, 0.047), 0.153	
Eye oedema, n (%)	0	0	1 (1.9)	1 (1.0)	0.997
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.535 (0.033, 8.732), 0.656	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.540 (0.034, 8.464), 0.661	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.009 (-0.049, 0.032), 0.683	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.2a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

	Male		Female		
Preferred Term	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [3]
Generalised oedema, n (%)	0	0	0	1 (1.0)	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.461	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.010, 0.030), 0.315	
Oedema, n (%)	0	0	0	1 (1.0)	0.972
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.461	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.010 (-0.010, 0.030), 0.315	
Eye swelling, n (%)	0	0	1 (1.9)	0	0.964
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.172	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.019 (-0.054, 0.017), 0.313	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.2a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

	Male		Female		
Preferred Term	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.2a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

	Male		Female		
Preferred Term	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.2a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

	Male		Female		
Preferred Term	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.3a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Preferred Term	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [3]
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	5 (15.2)	15 (25.0)	3 (7.9)	21 (25.9)	0.366
Odds Ratio (95% CIs) [1], P-Value		1.867 (0.611, 5.702), 0.269		4.083 (1.136, 14.679), 0.022	
Relative Risk (95% CIs) [2], P-Value		1.650 (0.658, 4.135), 0.285		3.284 (1.043, 10.337), 0.042	
Risk Difference (95% CIs) [2], P-Value		0.098 (-0.066, 0.263), 0.240		0.180 (0.052, 0.309), 0.006	
Oedema peripheral, n (%)	2 (6.1)	6 (10.0)	1 (2.6)	6 (7.4)	0.696
Odds Ratio (95% CIs) [1], P-Value		1.722 (0.327, 9.059), 0.517		2.960 (0.344, 25.495), 0.302	
Relative Risk (95% CIs) [2], P-Value		1.650 (0.353, 7.719), 0.525		2.815 (0.351, 22.568), 0.330	
Risk Difference (95% CIs) [2], P-Value		0.039 (-0.072, 0.151), 0.488		0.048 (-0.029, 0.124), 0.221	
Face oedema, n (%)	1 (3.0)	5 (8.3)	0	5 (6.2)	0.954
Odds Ratio (95% CIs) [1], P-Value		2.909 (0.325, 26.014), 0.319		NE (NE, NE), 0.118	
Relative Risk (95% CIs) [2], P-Value		2.750 (0.335, 22.560), 0.346		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.038, 0.144), 0.254		0.062 (0.009, 0.114), 0.021	
Periorbital oedema, n (%)	1 (3.0)	5 (8.3)	1 (2.6)	4 (4.9)	0.795
Odds Ratio (95% CIs) [1], P-Value		2.909 (0.325, 26.014), 0.319		1.922 (0.207, 17.806), 0.559	
Relative Risk (95% CIs) [2], P-Value		2.750 (0.335, 22.560), 0.346		1.877 (0.217, 16.225), 0.567	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.038, 0.144), 0.254		0.023 (-0.046, 0.092), 0.515	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.3a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Preferred Term	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [3]
Eyelid oedema, n (%)	0	0	1 (2.6)	5 (6.2)	0.996
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		2.434 (0.274, 21.592), 0.410	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		2.346 (0.284, 19.390), 0.429	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.035 (-0.038, 0.108), 0.342	
Fluid retention, n (%)	0	1 (1.7)	0	1 (1.2)	0.999
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.456		NE (NE, NE), 0.492	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.017 (-0.016, 0.049), 0.313		0.012 (-0.012, 0.036), 0.314	
Swelling of eyelid, n (%)	0	2 (3.3)	0	0	0.966
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.289		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.033 (-0.012, 0.079), 0.150		NA (NA, NA), NA	
Eye oedema, n (%)	1 (3.0)	0	0	1 (1.2)	0.919
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.175		NE (NE, NE), 0.492	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.030 (-0.089, 0.028), 0.310		0.012 (-0.012, 0.036), 0.314	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.3a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Preferred Term	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [3]
Generalised oedema, n (%)	0	0	0	1 (1.2)	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.492	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.012 (-0.012, 0.036), 0.314	
Oedema, n (%)	0	0	0	1 (1.2)	0.967
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.492	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.012 (-0.012, 0.036), 0.314	
Eye swelling, n (%)	1 (3.0)	0	0	0	0.969
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.175		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.030 (-0.089, 0.028), 0.310		NA (NA, NA), NA	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.3a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Preferred Term	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.3a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Preferred Term	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.3a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

	North America		Europe		
Preferred Term	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	4 (14.3)	11 (21.2)	1 (6.7)	4 (21.1)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	2 (7.1)	5 (9.6)	0	1 (5.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	2 (3.8)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Periorbital oedema, n (%)	1 (3.6)	4 (7.7)	0	1 (5.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France Placebo (N=6)	France Avapritinib 25 mg (N=11)	Spain Placebo (N=3)	Spain Avapritinib 25 mg (N=14)
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	0	2 (18.2)	0	7 (50.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	0	0	0	2 (14.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	1 (9.1)	0	2 (14.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Periorbital oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom		Canada	
	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=8)
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	0	2 (18.2)	1 (20.0)	4 (50.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	0	1 (9.1)	0	1 (12.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	1 (9.1)	1 (20.0)	3 (37.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Periorbital oedema, n (%)	0	1 (9.1)	0	1 (12.5)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	0	1 (11.1)	0	2 (40.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	0	0	0	1 (20.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Periorbital oedema, n (%)	0	0	0	1 (20.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium		Italy	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=0)	Avapritinib 25 mg (N=4)
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	0	1 (33.3)	0	1 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	0	1 (33.3)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	1 (33.3)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Periorbital oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden		Switzerland	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=2)
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	1 (100.0)	0	1 (100.0)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema peripheral, n (%)	1 (100.0)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Face oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Periorbital oedema, n (%)	0	0	1 (100.0)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	0	1 (100.0)	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Oedema peripheral, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Face oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Periorbital oedema, n (%)	0	1 (100.0)	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Eyelid oedema, n (%)	0	0	1 (6.7)	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Fluid retention, n (%)	0	1 (1.9)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling of eyelid, n (%)	0	2 (3.8)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye oedema, n (%)	1 (3.6)	0	0	1 (5.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France		Spain	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=3)	Avapritinib 25 mg (N=14)
Eyelid oedema, n (%)	0	1 (9.1)	0	4 (28.6)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Fluid retention, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling of eyelid, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Eyelid oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Fluid retention, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling of eyelid, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands		Norway	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)
Eyelid oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Fluid retention, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling of eyelid, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium		Italy	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=0)	Avapritinib 25 mg (N=4)
Eyelid oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Fluid retention, n (%)	0	0	0	1 (25.0)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling of eyelid, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden		Switzerland	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=2)
Eyelid oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Fluid retention, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling of eyelid, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Eyelid oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Fluid retention, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Swelling of eyelid, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Eye oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Generalised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema, n (%)	0	0	0	1 (5.3)
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye swelling, n (%)	1 (3.6)	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Abdominal wall oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France		Spain	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=3)	Avapritinib 25 mg (N=14)
Generalised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Abdominal wall oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom		Canada	
	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=8)
Generalised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Abdominal wall oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Generalised oedema, n (%)	0	1 (11.1)	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Abdominal wall oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium		Italy	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=0)	Avapritinib 25 mg (N=4)
Generalised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Abdominal wall oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden		Switzerland	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=2)
Generalised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Eye swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Abdominal wall oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Generalised oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Eye swelling, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Abdominal wall oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Capillary leak syndrome, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Extensive interdialytic weight gain, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Gravitational oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hydraemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

	France		Spain	
System Organ Class Preferred Term	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=3)	Avapritinib 25 mg (N=14)
Capillary leak syndrome, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Extensive interdialytic weight gain, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Gravitational oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hydraemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom		Canada	
	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=8)
Capillary leak syndrome, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Extensive interdialytic weight gain, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Gravitational oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hydraemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands Placebo (N=3)	Netherlands Avapritinib 25 mg (N=9)	Norway Placebo (N=3)	Norway Avapritinib 25 mg (N=5)
Capillary leak syndrome, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Extensive interdialytic weight gain, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Gravitational oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hydraemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium		Italy	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=0)	Avapritinib 25 mg (N=4)
Capillary leak syndrome, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Extensive interdialytic weight gain, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Gravitational oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hydraemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden		Switzerland	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=2)
Capillary leak syndrome, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Extensive interdialytic weight gain, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Gravitational oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Hydraemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States		Germany	
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Placebo (N=15)	Avapritinib 25 mg (N=19)
Hypervolaemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Localised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Non-pitting oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema blister, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France		Spain	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=3)	Avapritinib 25 mg (N=14)
Hypervolaemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Localised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Non-pitting oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema blister, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom		Canada	
	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=8)
Hypervolaemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Localised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Non-pitting oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema blister, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands		Norway	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)
Hypervolaemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Localised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Non-pitting oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema blister, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium		Italy	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=0)	Avapritinib 25 mg (N=4)
Hypervolaemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Localised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Non-pitting oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema blister, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden		Switzerland	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=2)
Hypervolaemia, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Localised oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Non-pitting oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Oedema blister, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Hypervolaemia, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United States Placebo (N=28)	United States Avapritinib 25 mg (N=52)	Germany Placebo (N=15)	Germany Avapritinib 25 mg (N=19)
Periorbital swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Stoma site oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling face, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Visceral oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	France		Spain	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=3)	Avapritinib 25 mg (N=14)
Periorbital swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Stoma site oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling face, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Visceral oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	United Kingdom Placebo (N=5)	United Kingdom Avapritinib 25 mg (N=11)	Canada Placebo (N=5)	Canada Avapritinib 25 mg (N=8)
Periorbital swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Stoma site oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling face, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Visceral oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Netherlands		Norway	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)
Periorbital swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Stoma site oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling face, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Visceral oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Belgium		Italy	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=0)	Avapritinib 25 mg (N=4)
Periorbital swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Stoma site oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling face, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Visceral oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Sweden		Switzerland	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=2)
Periorbital swelling, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Stoma site oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Swelling face, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Visceral oedema, n (%)	0	0	0	0
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.9a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

System Organ Class Preferred Term	Denmark Placebo (N=0)	Denmark Avapritinib 25 mg (N=1)	P-Value [3]
Periorbital swelling, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Swelling face, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-country-a.sas Date: 11:51/20JUL2023

Table 35.3.1.16.2.1.1.4a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Preferred Term	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [3]
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	2 (7.7)	10 (19.2)	6 (13.3)	26 (29.9)	0.974
Odds Ratio (95% CIs) [1], P-Value		2.857 (0.577, 14.136), 0.183		2.770 (1.046, 7.341), 0.035	
Relative Risk (95% CIs) [2], P-Value		2.500 (0.590, 10.587), 0.213		2.241 (0.996, 5.046), 0.051	
Risk Difference (95% CIs) [2], P-Value		0.115 (-0.033, 0.264), 0.127		0.166 (0.027, 0.304), 0.019	
Oedema peripheral, n (%)	1 (3.8)	5 (9.6)	2 (4.4)	7 (8.0)	0.804
Odds Ratio (95% CIs) [1], P-Value		2.660 (0.294, 24.031), 0.367		1.881 (0.374, 9.455), 0.436	
Relative Risk (95% CIs) [2], P-Value		2.500 (0.308, 20.309), 0.391		1.810 (0.392, 8.358), 0.447	
Risk Difference (95% CIs) [2], P-Value		0.058 (-0.051, 0.167), 0.300		0.036 (-0.047, 0.119), 0.395	
Face oedema, n (%)	0	4 (7.7)	1 (2.2)	6 (6.9)	0.961
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.147		3.259 (0.380, 27.941), 0.256	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		3.103 (0.385, 24.996), 0.287	
Risk Difference (95% CIs) [2], P-Value		0.077 (0.004, 0.149), 0.037		0.047 (-0.022, 0.115), 0.181	
Periorbital oedema, n (%)	1 (3.8)	1 (1.9)	1 (2.2)	8 (9.2)	0.219
Odds Ratio (95% CIs) [1], P-Value		0.490 (0.029, 8.165), 0.612		4.456 (0.539, 36.799), 0.132	
Relative Risk (95% CIs) [2], P-Value		0.500 (0.033, 7.678), 0.619		4.138 (0.534, 32.062), 0.174	
Risk Difference (95% CIs) [2], P-Value		-0.019 (-0.102, 0.064), 0.649		0.070 (-0.005, 0.144), 0.066	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.4a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Preferred Term	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [3]
Eyelid oedema, n (%)	0	1 (1.9)	1 (2.2)	4 (4.6)	0.959
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.477		2.120 (0.230, 19.555), 0.498	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.069 (0.238, 17.968), 0.510	
Risk Difference (95% CIs) [2], P-Value		0.019 (-0.018, 0.057), 0.313		0.024 (-0.038, 0.085), 0.450	
Fluid retention, n (%)	0	0	0	2 (2.3)	0.970
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.305	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.023 (-0.009, 0.054), 0.153	
Swelling of eyelid, n (%)	0	0	0	2 (2.3)	0.970
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.305	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.023 (-0.009, 0.054), 0.153	
Eye oedema, n (%)	0	1 (1.9)	1 (2.2)	0	0.924
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.477		NE (NE, NE), 0.163	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.019 (-0.018, 0.057), 0.313		-0.022 (-0.065, 0.021), 0.312	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.4a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Preferred Term	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [3]
Generalised oedema, n (%)	0	0	0	1 (1.1)	0.968
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.470	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.011 (-0.011, 0.034), 0.315	
Oedema, n (%)	0	0	0	1 (1.1)	0.968
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.470	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.011 (-0.011, 0.034), 0.315	
Eye swelling, n (%)	0	0	1 (2.2)	0	0.962
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.163	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.022 (-0.065, 0.021), 0.312	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.4a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Preferred Term	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.4a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Preferred Term	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.4a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
Preferred Term	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.5a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Preferred Term	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [3]
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	2 (13.3)	6 (21.4)	6 (10.7)	30 (26.5)	0.600
Odds Ratio (95% CIs) [1], P-Value		1.773 (0.311, 10.110), 0.516		3.012 (1.172, 7.743), 0.018	
Relative Risk (95% CIs) [2], P-Value		1.607 (0.369, 7.006), 0.528		2.478 (1.096, 5.603), 0.029	
Risk Difference (95% CIs) [2], P-Value		0.081 (-0.149, 0.311), 0.489		0.158 (0.043, 0.273), 0.007	
Oedema peripheral, n (%)	1 (6.7)	2 (7.1)	2 (3.6)	10 (8.8)	0.552
Odds Ratio (95% CIs) [1], P-Value		1.077 (0.090, 12.948), 0.953		2.621 (0.554, 12.394), 0.209	
Relative Risk (95% CIs) [2], P-Value		1.071 (0.106, 10.871), 0.953		2.478 (0.562, 10.929), 0.231	
Risk Difference (95% CIs) [2], P-Value		0.005 (-0.153, 0.163), 0.953		0.053 (-0.019, 0.124), 0.148	
Face oedema, n (%)	0	3 (10.7)	1 (1.8)	7 (6.2)	0.970
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.189		3.632 (0.436, 30.273), 0.204	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		3.469 (0.437, 27.510), 0.239	
Risk Difference (95% CIs) [2], P-Value		0.107 (-0.007, 0.222), 0.067		0.044 (-0.012, 0.100), 0.125	
Periorbital oedema, n (%)	0	1 (3.6)	2 (3.6)	8 (7.1)	0.972
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.459		2.057 (0.422, 10.026), 0.363	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.982 (0.435, 9.028), 0.376	
Risk Difference (95% CIs) [2], P-Value		0.036 (-0.033, 0.104), 0.309		0.035 (-0.033, 0.103), 0.311	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.5a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Preferred Term	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [3]
Eyelid oedema, n (%)	0	0	1 (1.8)	5 (4.4)	0.997
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		2.546 (0.290, 22.333), 0.383	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		2.478 (0.297, 20.706), 0.402	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.026 (-0.025, 0.078), 0.314	
Fluid retention, n (%)	0	1 (3.6)	0	1 (0.9)	0.997
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.459		NE (NE, NE), 0.480	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.036 (-0.033, 0.104), 0.309		0.009 (-0.008, 0.026), 0.315	
Swelling of eyelid, n (%)	0	0	0	2 (1.8)	0.976
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.317	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.018 (-0.007, 0.042), 0.154	
Eye oedema, n (%)	0	0	1 (1.8)	1 (0.9)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.491 (0.030, 7.999), 0.610	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.496 (0.032, 7.777), 0.617	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.009 (-0.048, 0.030), 0.649	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.5a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Preferred Term	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [3]
Generalised oedema, n (%)	0	0	0	1 (0.9)	0.975
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.480	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.009 (-0.008, 0.026), 0.315	
Oedema, n (%)	0	1 (3.6)	0	0	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.459		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.036 (-0.033, 0.104), 0.309		NA (NA, NA), NA	
Eye swelling, n (%)	1 (6.7)	0	0	0	0.972
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.167		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.067 (-0.193, 0.060), 0.301		NA (NA, NA), NA	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.5a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Preferred Term	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.5a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Preferred Term	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.5a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
Preferred Term	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.6a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Preferred Term	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [3]
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	2 (5.7)	17 (23.6)	6 (16.7)	19 (27.5)	0.293
Odds Ratio (95% CIs) [1], P-Value		5.100 (1.107, 23.492), 0.023		1.900 (0.683, 5.287), 0.215	
Relative Risk (95% CIs) [2], P-Value		4.132 (1.010, 16.897), 0.048		1.652 (0.724, 3.769), 0.233	
Risk Difference (95% CIs) [2], P-Value		0.179 (0.054, 0.304), 0.005		0.109 (-0.052, 0.270), 0.186	
Oedema peripheral, n (%)	1 (2.9)	5 (6.9)	2 (5.6)	7 (10.1)	0.841
Odds Ratio (95% CIs) [1], P-Value		2.537 (0.285, 22.589), 0.389		1.919 (0.377, 9.759), 0.425	
Relative Risk (95% CIs) [2], P-Value		2.431 (0.295, 20.022), 0.409		1.826 (0.400, 8.340), 0.437	
Risk Difference (95% CIs) [2], P-Value		0.041 (-0.040, 0.121), 0.320		0.046 (-0.057, 0.149), 0.384	
Face oedema, n (%)	0	5 (6.9)	1 (2.8)	5 (7.2)	0.955
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.110		2.734 (0.307, 24.340), 0.349	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.609 (0.317, 21.493), 0.373	
Risk Difference (95% CIs) [2], P-Value		0.069 (0.011, 0.128), 0.020		0.045 (-0.037, 0.126), 0.282	
Periorbital oedema, n (%)	0	2 (2.8)	2 (5.6)	7 (10.1)	0.958
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.320		1.919 (0.377, 9.759), 0.425	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.826 (0.400, 8.340), 0.437	
Risk Difference (95% CIs) [2], P-Value		0.028 (-0.010, 0.066), 0.151		0.046 (-0.057, 0.149), 0.384	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.6a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Preferred Term	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [3]
Eyelid oedema, n (%)	1 (2.9)	1 (1.4)	0	4 (5.8)	0.938
Odds Ratio (95% CIs) [1], P-Value		0.479 (0.029, 7.889), 0.599		NE (NE, NE), 0.141	
Relative Risk (95% CIs) [2], P-Value		0.486 (0.031, 7.545), 0.606		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.015 (-0.076, 0.047), 0.640		0.058 (0.003, 0.113), 0.039	
Fluid retention, n (%)	0	2 (2.8)	0	0	0.952
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.320		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.028 (-0.010, 0.066), 0.151		NA (NA, NA), NA	
Swelling of eyelid, n (%)	0	1 (1.4)	0	1 (1.4)	>0.999
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.484		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.014 (-0.013, 0.041), 0.314		0.014 (-0.014, 0.043), 0.314	
Eye oedema, n (%)	0	1 (1.4)	1 (2.8)	0	0.919
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.484		NE (NE, NE), 0.164	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.014 (-0.013, 0.041), 0.314		-0.028 (-0.081, 0.026), 0.310	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.6a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Preferred Term	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [3]
Generalised oedema, n (%)	0	1 (1.4)	0	0	0.966
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.484		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.014 (-0.013, 0.041), 0.314		NA (NA, NA), NA	
Oedema, n (%)	0	1 (1.4)	0	0	0.966
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.484		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.014 (-0.013, 0.041), 0.314		NA (NA, NA), NA	
Eye swelling, n (%)	0	0	1 (2.8)	0	0.956
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.164	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.028 (-0.081, 0.026), 0.310	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.6a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Preferred Term	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.6a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Preferred Term	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.6a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
Preferred Term	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.7a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [3]
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	0	5 (26.3)	8 (12.5)	31 (25.4)	0.960
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.131		2.385 (1.024, 5.554), 0.040	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.033 (0.993, 4.159), 0.052	
Risk Difference (95% CIs) [2], P-Value		0.263 (0.065, 0.461), 0.009		0.129 (0.017, 0.241), 0.024	
Oedema peripheral, n (%)	0	2 (10.5)	3 (4.7)	10 (8.2)	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.372		1.815 (0.481, 6.846), 0.373	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.749 (0.499, 6.129), 0.383	
Risk Difference (95% CIs) [2], P-Value		0.105 (-0.033, 0.243), 0.135		0.035 (-0.036, 0.106), 0.333	
Face oedema, n (%)	0	2 (10.5)	1 (1.6)	8 (6.6)	0.956
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.372		4.421 (0.541, 36.157), 0.132	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		4.197 (0.537, 32.820), 0.172	
Risk Difference (95% CIs) [2], P-Value		0.105 (-0.033, 0.243), 0.135		0.050 (-0.003, 0.103), 0.067	
Periorbital oedema, n (%)	0	1 (5.3)	2 (3.1)	8 (6.6)	0.956
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.536		2.175 (0.448, 10.562), 0.324	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.098 (0.459, 9.591), 0.339	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		0.034 (-0.027, 0.096), 0.272	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.7a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [3]
Eyelid oedema, n (%)	0	0	1 (1.6)	5 (4.1)	0.995
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		2.692 (0.308, 23.551), 0.352	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		2.623 (0.313, 21.975), 0.374	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.025 (-0.021, 0.072), 0.285	
Fluid retention, n (%)	0	0	0	2 (1.6)	0.974
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.303	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.016 (-0.006, 0.039), 0.154	
Swelling of eyelid, n (%)	0	1 (5.3)	0	1 (0.8)	0.997
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.536		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		0.008 (-0.008, 0.024), 0.315	
Eye oedema, n (%)	0	0	1 (1.6)	1 (0.8)	0.998
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		0.521 (0.032, 8.464), 0.641	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		0.525 (0.033, 8.249), 0.646	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.007 (-0.042, 0.027), 0.672	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.7a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [3]
Generalised oedema, n (%)	0	0	0	1 (0.8)	0.981
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.468	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.008 (-0.008, 0.024), 0.315	
Oedema, n (%)	0	1 (5.3)	0	0	0.959
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.536		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		0.053 (-0.048, 0.153), 0.304		NA (NA, NA), NA	
Eye swelling, n (%)	0	0	1 (1.6)	0	0.980
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.166	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		-0.016 (-0.046, 0.015), 0.313	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.7a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.7a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.7a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.8a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [3]
Patients with at least one Grade 1 and 2 Oedema CMQ, n (%)	2 (18.2)	6 (23.1)	6 (10.0)	30 (26.1)	0.406
Odds Ratio (95% CIs) [1], P-Value		1.350 (0.227, 8.031), 0.741		3.176 (1.240, 8.136), 0.012	
Relative Risk (95% CIs) [2], P-Value		1.269 (0.302, 5.339), 0.745		2.609 (1.150, 5.917), 0.022	
Risk Difference (95% CIs) [2], P-Value		0.049 (-0.231, 0.329), 0.731		0.161 (0.050, 0.271), 0.004	
Oedema peripheral, n (%)	0	2 (7.7)	3 (5.0)	10 (8.7)	0.955
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.344		1.810 (0.479, 6.841), 0.376	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		1.739 (0.497, 6.082), 0.386	
Risk Difference (95% CIs) [2], P-Value		0.077 (-0.026, 0.179), 0.141		0.037 (-0.038, 0.112), 0.337	
Face oedema, n (%)	0	4 (15.4)	1 (1.7)	6 (5.2)	0.960
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.168		3.248 (0.382, 27.620), 0.255	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		3.130 (0.386, 25.407), 0.285	
Risk Difference (95% CIs) [2], P-Value		0.154 (0.015, 0.293), 0.030		0.036 (-0.016, 0.087), 0.181	
Periorbital oedema, n (%)	0	1 (3.8)	2 (3.3)	8 (7.0)	0.964
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.510		2.168 (0.446, 10.549), 0.327	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		2.087 (0.457, 9.520), 0.342	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.035, 0.112), 0.308		0.036 (-0.029, 0.101), 0.275	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.8a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [3]
Eyelid oedema, n (%)	0	0	1 (1.7)	5 (4.3)	0.996
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		2.682 (0.306, 23.493), 0.355	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		2.609 (0.312, 21.825), 0.376	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.027 (-0.023, 0.076), 0.287	
Fluid retention, n (%)	0	1 (3.8)	0	1 (0.9)	0.998
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.510		NE (NE, NE), 0.469	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		0.038 (-0.035, 0.112), 0.308		0.009 (-0.008, 0.026), 0.315	
Swelling of eyelid, n (%)	0	0	0	2 (1.7)	0.968
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.304	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.017 (-0.007, 0.041), 0.154	
Eye oedema, n (%)	1 (9.1)	0	0	1 (0.9)	0.900
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.119		NE (NE, NE), 0.469	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		-0.091 (-0.261, 0.079), 0.294		0.009 (-0.008, 0.026), 0.315	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.8a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [3]
Generalised oedema, n (%)	0	0	0	1 (0.9)	0.977
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.469	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.009 (-0.008, 0.026), 0.315	
Oedema, n (%)	0	0	0	1 (0.9)	0.977
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NE (NE, NE), 0.469	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NE (NE, NE), NE	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		0.009 (-0.008, 0.026), 0.315	
Eye swelling, n (%)	1 (9.1)	0	0	0	0.963
Odds Ratio (95% CIs) [1], P-Value		NE (NE, NE), 0.119		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NE (NE, NE), NE		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		-0.091 (-0.261, 0.079), 0.294		NA (NA, NA), NA	
Abdominal wall oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.8a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [3]
Capillary leak syndrome, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Extensive interdialytic weight gain, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Gravitational oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Hydraemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.8a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [3]
Hypervolaemia, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Localised oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Non-pitting oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Oedema blister, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.1.1.8a
Summary of Grade 1 and 2 Oedema CMQ by Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

	Yes		No		
Preferred Term	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [3]
Periorbital swelling, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Stoma site oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Swelling face, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Visceral oedema, n (%)	0	0	0	0	-
Odds Ratio (95% CIs) [1], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Relative Risk (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	
Risk Difference (95% CIs) [2], P-Value		NA (NA, NA), NA		NA (NA, NA), NA	

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd1_2-subgrp-a.sas Date: 17:15/05MAY2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.16.2.2.1.1a
Summary of Grade 3 and Higher Oedema CMQ by Preferred Term by Age Group
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd3-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.2.1.2a
Summary of Grade 3 and Higher Oedema CMQ by Preferred Term by Sex
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd3-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.2.1.3a
Summary of Grade 3 and Higher Oedema CMQ by Preferred Term by Region
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd3-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.2.1.9a
Summary of Grade 3 and Higher Oedema CMQ by Preferred Term by Country
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd3-country-a.sas Date: 11:51/20JUL2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.16.2.2.1.4a
Summary of Grade 3 and Higher Oedema CMQ by Preferred Term by Baseline ISM Status
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd3-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.2.1.5a
Summary of Grade 3 and Higher Oedema CMQ by Preferred Term by Baseline Serum Tryptase Level
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd3-subgrp-a.sas Date: 17:15/05MAY2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.16.2.2.1.6a
Summary of Grade 3 and Higher Oedema CMQ by Preferred Term by Baseline Best Supportive Care (BSC)
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd3-subgrp-a.sas Date: 17:15/05MAY2023

Table 35.3.1.16.2.2.1.7a
Summary of Grade 3 and Higher Oedema CMQ by Preferred Term by Prior Cytoreductive Therapy
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd3-subgrp-a.sas Date: 17:15/05MAY2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.16.2.2.1.8a
Summary of Grade 3 and Higher Oedema CMQ by Preferred Term by Baseline Opioid Use
Safety Population, Part 2 (Part 2 Baseline)

There are no observations for this output

Note1: Adverse events are coded using MedDRA version 25.0.
Note2: A patient is counted only once for multiple events within the same preferred term.
Note3: All Adverse Events are Treatment Emergent Adverse Events.
[1] Odds Ratio (OR) is to compare Avapritinib 25 mg with Placebo using odds ratio chi-square test. OR > 1 suggests a higher chance of the event in Avapritinib 25 mg compared to placebo.
[2] Relative Risk (RR) and Risk Difference (RD) are to compare Avapritinib 25 mg with Placebo using two-sample proportions test. RR>1 or RD>0 suggest a higher chance of the event in Avapritinib 25 mg compared to placebo.
[3] Two-sided p-values for treatment-by-subgroup interaction are from logistic regression with treatment, subgroup, treatment*subgroup in the model.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-grd3-subgrp-a.sas Date: 17:15/05MAY2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.16.6.1.1a
Time to Onset of Oedema CMQ by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	<65 Years		>=65 Years		
	Placebo (N=60)	Avapritinib 25 mg (N=132)	Placebo (N=11)	Avapritinib 25 mg (N=9)	P-Value [2]
Patients with Events (n (%))	8 (13.3)	30 (22.7)	0	6 (66.7)	NA
Patients Censored (n (%))	52 (86.7)	102 (77.3)	11 (100)	3 (33.3)	
Kaplan-Meier Estimates (Months)					
Median (95% CI)	6.34 (-, -)	- (-, -)	- (-, -)	4.67 (1.18, -)	
25th, 75th percentiles	6.34, 6.34	-, -	-, -	1.18, -	
Min, Max	0.10, 6.34	0.03, 6.51*	1.87*, 5.59*	0.26, 5.65*	
3 Months (95% CI)	8.3 (1.3, 15.3)	17.6 (11.1, 24.2)	0.0 (0.0, 0.0)	44.4 (12.0, 76.9)	
6 Months (95% CI)	12.1 (3.7, 20.6)	23.3 (16.0, 30.7)	- (-, -)	- (-, -)	
9 Months (95% CI)	100 (100, 100)	- (-, -)	- (-, -)	- (-, -)	
12 Months (95% CI)	100 (100, 100)	- (-, -)	- (-, -)	- (-, -)	
Hazard Ratio (95% CI) [1]		1.800 (0.825, 3.927)		- (-, -)	
p-value		0.1396		NA	

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-tte-itt-subgrp-a.sas Date: 15:03/05SEP2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.16.6.1.2a
Time to Onset of Oedema CMQ by Sex
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Male		Female		
	Placebo (N=17)	Avapritinib 25 mg (N=41)	Placebo (N=54)	Avapritinib 25 mg (N=100)	P-Value [2]
Patients with Events (n (%))	1 (5.9)	9 (22.0)	7 (13.0)	27 (27.0)	0.612
Patients Censored (n (%))	16 (94.1)	32 (78.0)	47 (87.0)	73 (73.0)	
Kaplan-Meier Estimates (Months)					
Median (95% CI)	- (-, -)	- (-, -)	6.34 (-, -)	- (-, -)	
25th, 75th percentiles	-, -	-, -	6.34, 6.34	4.86, -	
Min, Max	1.77, 6.21*	0.49, 6.05*	0.10, 6.34	0.03, 6.51*	
3 Months (95% CI)	5.9 (0.0, 17.1)	17.1 (5.6, 28.6)	7.4 (0.4, 14.4)	20.3 (12.3, 28.3)	
6 Months (95% CI)	5.9 (0.0, 17.1)	22.0 (9.3, 34.6)	11.7 (2.8, 20.6)	27.9 (18.9, 36.9)	
9 Months (95% CI)	- (-, -)	- (-, -)	100 (100, 100)	- (-, -)	
12 Months (95% CI)	- (-, -)	- (-, -)	100 (100, 100)	- (-, -)	
Hazard Ratio (95% CI) [1]		4.012 (0.508, 31.676)		2.247 (0.978, 5.161)	
p-value		0.1875		0.0565	

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-tte-itt-subgrp-a.sas Date: 15:03/05SEP2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.16.6.1.3a
Time to Onset of Oedema CMQ by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	North America		Europe		
	Placebo (N=33)	Avapritinib 25 mg (N=60)	Placebo (N=38)	Avapritinib 25 mg (N=81)	P-Value [2]
Patients with Events (n (%))	5 (15.2)	15 (25.0)	3 (7.9)	21 (25.9)	0.422
Patients Censored (n (%))	28 (84.8)	45 (75.0)	35 (92.1)	60 (74.1)	
Kaplan-Meier Estimates (Months)					
Median (95% CI)	6.34 (-, -)	- (-, -)	- (-, -)	- (-, -)	
25th, 75th percentiles	6.34, 6.34	4.86, -	-, -	5.22, -	
Min, Max	0.85, 6.34	0.03, 6.31*	0.10, 6.28*	0.26, 6.51*	
3 Months (95% CI)	6.1 (0.0, 14.2)	15.0 (6.0, 24.1)	7.9 (0.0, 16.5)	22.6 (13.4, 31.8)	
6 Months (95% CI)	13.1 (1.0, 25.3)	25.2 (14.2, 36.3)	7.9 (0.0, 16.5)	26.8 (16.9, 36.7)	
9 Months (95% CI)	100 (100, 100)	- (-, -)	- (-, -)	- (-, -)	
12 Months (95% CI)	100 (100, 100)	- (-, -)	- (-, -)	- (-, -)	
Hazard Ratio (95% CI) [1]		2.160 (0.717, 6.508)		3.529 (1.052, 11.834)	
p-value		0.1713		0.0411	

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-tte-itt-subgrp-a.sas Date: 15:03/05SEP2023

Table 35.3.1.16.6.1.9a
Time to Onset of Oedema CMQ by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	United States		Germany	
	Placebo (N=28)	Avapritinib 25 mg (N=52)	Placebo (N=15)	Avapritinib 25 mg (N=19)
Patients with Events (n (%))	4 (14.3)	11 (21.2)	1 (6.7)	4 (21.1)
Patients Censored (n (%))	24 (85.7)	41 (78.8)	14 (93.3)	15 (78.9)
Kaplan-Meier Estimates (Months)				
Median (95% CI)	6.34 (-, -)	- (-, -)	- (-, -)	- (-, -)
25th, 75th percentiles	6.34, 6.34	-, -	-, -	-, -
Min, Max	0.85, 6.34	0.03, 6.11*	0.26, 5.88*	0.43, 6.05*
3 Months (95% CI)	7.1 (0.0, 16.7)	11.6 (2.9, 20.3)	6.7 (0.0, 19.3)	15.8 (0.0, 32.2)
6 Months (95% CI)	11.8 (0.0, 24.5)	21.4 (10.2, 32.6)	- (-, -)	23.4 (2.8, 44.1)
9 Months (95% CI)	100 (100, 100)	- (-, -)	- (-, -)	- (-, -)
12 Months (95% CI)	100 (100, 100)	- (-, -)	- (-, -)	- (-, -)
Hazard Ratio (95% CI) [1]		2.033 (0.567, 7.289)		3.360 (0.374, 30.173)
p-value		0.2762		0.2792

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-tte-itt-subgrp-a.sas Date: 15:03/05SEP2023

Table 35.3.1.16.6.1.9a
Time to Onset of Oedema CMQ by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	France		Spain	
	Placebo (N=6)	Avapritinib 25 mg (N=11)	Placebo (N=3)	Avapritinib 25 mg (N=14)
Patients with Events (n (%))	0	2 (18.2)	0	7 (50.0)
Patients Censored (n (%))	6 (100)	9 (81.8)	3 (100)	7 (50.0)
Kaplan-Meier Estimates (Months)				
Median (95% CI)	- (-, -)	- (-, -)	- (-, -)	- (1.97, -)
25th, 75th percentiles	-, -	-, -	-, -	1.97, -
Min, Max	5.45*, 5.55*	1.51, 5.72*	5.55*, 6.24*	0.26, 6.41*
3 Months (95% CI)	0.0 (0.0, 0.0)	9.1 (0.0, 26.1)	0.0 (0.0, 0.0)	42.9 (16.9, 68.8)
6 Months (95% CI)	- (-, -)	- (-, -)	0.0 (0.0, 0.0)	50.0 (23.8, 76.2)
9 Months (95% CI)	- (-, -)	- (-, -)	- (-, -)	- (-, -)
12 Months (95% CI)	- (-, -)	- (-, -)	- (-, -)	- (-, -)
Hazard Ratio (95% CI) [1]		- (-, -)		- (-, -)
p-value		NA		NA

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-tte-itt-subgrp-a.sas Date: 15:03/05SEP2023

Table 35.3.1.16.6.1.9a
Time to Onset of Oedema CMQ by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	United Kingdom		Canada	
	Placebo (N=5)	Avapritinib 25 mg (N=11)	Placebo (N=5)	Avapritinib 25 mg (N=8)
Patients with Events (n (%))	0	2 (18.2)	1 (20.0)	4 (50.0)
Patients Censored (n (%))	5 (100)	9 (81.8)	4 (80.0)	4 (50.0)
Kaplan-Meier Estimates (Months)				
Median (95% CI)	- (-, -)	- (-, -)	- (3.42, -)	- (1.28, -)
25th, 75th percentiles	-, -	-, -	-, -	1.43, -
Min, Max	5.55*, 6.28*	0.49, 6.51*	3.42, 5.59*	0.92, 6.31*
3 Months (95% CI)	0.0 (0.0, 0.0)	18.2 (0.0, 41.0)	0.0 (0.0, 0.0)	37.5 (4.0, 71.0)
6 Months (95% CI)	0.0 (0.0, 0.0)	18.2 (0.0, 41.0)	- (-, -)	50.0 (15.4, 84.6)
9 Months (95% CI)	- (-, -)	- (-, -)	- (-, -)	- (-, -)
12 Months (95% CI)	- (-, -)	- (-, -)	- (-, -)	- (-, -)
Hazard Ratio (95% CI) [1]		- (-, -)		2.995 (0.333, 26.974)
p-value		NA		0.3279

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-tte-itt-subgrp-a.sas Date: 15:03/05SEP2023

Table 35.3.1.16.6.1.9a
Time to Onset of Oedema CMQ by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Netherlands		Norway	
	Placebo (N=3)	Avapritinib 25 mg (N=9)	Placebo (N=3)	Avapritinib 25 mg (N=5)
Patients with Events (n (%))	0	1 (11.1)	0	2 (40.0)
Patients Censored (n (%))	3 (100)	8 (88.9)	3 (100)	3 (60.0)
Kaplan-Meier Estimates (Months)				
Median (95% CI)	- (-, -)	- (-, -)	- (-, -)	- (2.79, -)
25th, 75th percentiles	-, -	-, -	-, -	2.99, -
Min, Max	5.52*, 5.55*	0.95*, 5.59*	5.45*, 5.45*	2.79, 5.55*
3 Months (95% CI)	0.0 (0.0, 0.0)	12.5 (0.0, 35.4)	0.0 (0.0, 0.0)	40.0 (0.0, 82.9)
6 Months (95% CI)	- (-, -)	- (-, -)	- (-, -)	- (-, -)
9 Months (95% CI)	- (-, -)	- (-, -)	- (-, -)	- (-, -)
12 Months (95% CI)	- (-, -)	- (-, -)	- (-, -)	- (-, -)
Hazard Ratio (95% CI) [1]		- (-, -)		- (-, -)
p-value		NA		NA

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-tte-itt-subgrp-a.sas Date: 15:03/05SEP2023

Table 35.3.1.16.6.1.9a
Time to Onset of Oedema CMQ by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Belgium		Italy	
	Placebo (N=1)	Avapritinib 25 mg (N=3)	Placebo (N=0)	Avapritinib 25 mg (N=4)
Patients with Events (n (%))	0	1 (33.3)	0	1 (25.0)
Patients Censored (n (%))	1 (100)	2 (66.7)	0	3 (75.0)
Kaplan-Meier Estimates (Months)				
Median (95% CI)	- (-, -)	- (2.43, -)	- (-, -)	- (2.46, -)
25th, 75th percentiles	-, -	2.43, -	-, -	-, -
Min, Max	5.45*, 5.45*	2.43, 5.55*	-, -	2.46, 5.55*
3 Months (95% CI)	0.0 (0.0, 0.0)	33.3 (0.0, 86.7)	- (-, -)	25.0 (0.0, 67.4)
6 Months (95% CI)	- (-, -)	- (-, -)	- (-, -)	- (-, -)
9 Months (95% CI)	- (-, -)	- (-, -)	- (-, -)	- (-, -)
12 Months (95% CI)	- (-, -)	- (-, -)	- (-, -)	- (-, -)
Hazard Ratio (95% CI) [1]		- (-, -)		- (-, -)
p-value		NA		NA

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-tte-itt-subgrp-a.sas Date: 15:03/05SEP2023

Table 35.3.1.16.6.1.9a
Time to Onset of Oedema CMQ by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Sweden		Switzerland	
	Placebo (N=1)	Avapritinib 25 mg (N=2)	Placebo (N=1)	Avapritinib 25 mg (N=2)
Patients with Events (n (%))	1 (100)	0	1 (100)	0
Patients Censored (n (%))	0	2 (100)	0	2 (100)
Kaplan-Meier Estimates (Months)				
Median (95% CI)	1.77 (-, -)	- (-, -)	0.10 (-, -)	- (-, -)
25th, 75th percentiles	1.77, 1.77	-, -	0.10, 0.10	-, -
Min, Max	1.77, 1.77	5.55*, 5.62*	0.10, 0.10	5.49*, 5.72*
3 Months (95% CI)	100 (100, 100)	0.0 (0.0, 0.0)	100 (100, 100)	0.0 (0.0, 0.0)
6 Months (95% CI)	100 (100, 100)	- (-, -)	100 (100, 100)	- (-, -)
9 Months (95% CI)	100 (100, 100)	- (-, -)	100 (100, 100)	- (-, -)
12 Months (95% CI)	100 (100, 100)	- (-, -)	100 (100, 100)	- (-, -)
Hazard Ratio (95% CI) [1]		- (-, -)	- (-, -)	
p-value		NA	NA	

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-tte-itt-subgrp-a.sas Date: 15:03/05SEP2023

Table 35.3.1.16.6.1.9a
Time to Onset of Oedema CMQ by Country
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Denmark		
	Placebo (N=0)	Avapritinib 25 mg (N=1)	P-Value [2]
Patients with Events (n (%))	0	1 (100)	NA
Patients Censored (n (%))	0	0	
Kaplan-Meier Estimates (Months)			
Median (95% CI)	- (-, -)	0.36 (-, -)	
25th, 75th percentiles	-, -	0.36, 0.36	
Min, Max	-, -	0.36, 0.36	
3 Months (95% CI)	- (-, -)	100 (100, 100)	
6 Months (95% CI)	- (-, -)	100 (100, 100)	
9 Months (95% CI)	- (-, -)	100 (100, 100)	
12 Months (95% CI)	- (-, -)	100 (100, 100)	
Hazard Ratio (95% CI) [1]		- (-, -)	
p-value		NA	

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-tte-itt-subgrp-a.sas Date: 15:03/05SEP2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.16.6.1.4a
Time to Onset of Oedema CMQ by Baseline ISM Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Moderate		Severe		
	Placebo (N=26)	Avapritinib 25 mg (N=52)	Placebo (N=45)	Avapritinib 25 mg (N=87)	P-Value [2]
Patients with Events (n (%))	2 (7.7)	10 (19.2)	6 (13.3)	26 (29.9)	0.980
Patients Censored (n (%))	24 (92.3)	42 (80.8)	39 (86.7)	61 (70.1)	
Kaplan-Meier Estimates (Months)					
Median (95% CI)	- (-, -)	- (-, -)	6.34 (-, -)	- (-, -)	
25th, 75th percentiles	-, -	-, -	6.34, 6.34	3.52, -	
Min, Max	0.10, 6.08*	0.43, 6.41*	0.26, 6.34	0.03, 6.51*	
3 Months (95% CI)	3.8 (0.0, 11.2)	13.5 (4.2, 22.7)	8.9 (0.6, 17.2)	23.4 (14.4, 32.3)	
6 Months (95% CI)	8.9 (0.0, 20.8)	19.2 (8.5, 29.9)	11.2 (1.9, 20.4)	30.9 (21.0, 40.8)	
9 Months (95% CI)	- (-, -)	- (-, -)	100 (100, 100)	- (-, -)	
12 Months (95% CI)	- (-, -)	- (-, -)	100 (100, 100)	- (-, -)	
Hazard Ratio (95% CI) [1]		2.588 (0.567, 11.818)		2.540 (1.044, 6.178)	
p-value		0.2196		0.0398	

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-tte-itt-subgrp-a.sas Date: 15:03/05SEP2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.16.6.1.5a
Time to Onset of Oedema CMQ by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	<20 ng/mL		>=20 ng/mL		
	Placebo (N=15)	Avapritinib 25 mg (N=28)	Placebo (N=56)	Avapritinib 25 mg (N=113)	P-Value [2]
Patients with Events (n (%))	2 (13.3)	6 (21.4)	6 (10.7)	30 (26.5)	0.675
Patients Censored (n (%))	13 (86.7)	22 (78.6)	50 (89.3)	83 (73.5)	
Kaplan-Meier Estimates (Months)					
Median (95% CI)	6.34 (-, -)	- (-, -)	- (-, -)	- (-, -)	
25th, 75th percentiles	6.34, 6.34	-, -	-, -	4.80, -	
Min, Max	1.77, 6.34	1.58, 6.11*	0.10, 6.28*	0.03, 6.51*	
3 Months (95% CI)	6.7 (0.0, 19.3)	14.3 (1.3, 27.2)	7.1 (0.4, 13.9)	20.6 (13.1, 28.1)	
6 Months (95% CI)	6.7 (0.0, 19.3)	22.4 (6.5, 38.4)	11.4 (2.7, 20.0)	27.0 (18.8, 35.3)	
9 Months (95% CI)	100 (100, 100)	- (-, -)	- (-, -)	- (-, -)	
12 Months (95% CI)	100 (100, 100)	- (-, -)	- (-, -)	- (-, -)	
Hazard Ratio (95% CI) [1]		3.253 (0.391, 27.050)		2.692 (1.120, 6.468)	
p-value		0.2751		0.0269	

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-tte-itt-subgrp-a.sas Date: 15:03/05SEP2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.16.6.1.6a
Time to Onset of Oedema CMQ by Baseline Best Supportive Care (BSC)
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Number of Baseline BSC <4		Number of Baseline BSC >=4		
	Placebo (N=35)	Avapritinib 25 mg (N=72)	Placebo (N=36)	Avapritinib 25 mg (N=69)	P-Value [2]
Patients with Events (n (%))	2 (5.7)	17 (23.6)	6 (16.7)	19 (27.5)	0.342
Patients Censored (n (%))	33 (94.3)	55 (76.4)	30 (83.3)	50 (72.5)	
Kaplan-Meier Estimates (Months)					
Median (95% CI)	- (-, -)	- (-, -)	6.34 (-, -)	- (-, -)	
25th, 75th percentiles	-, -	-, -	6.34, 6.34	4.67, -	
Min, Max	0.26, 5.88*	0.43, 6.41*	0.10, 6.34	0.03, 6.51*	
3 Months (95% CI)	5.7 (0.0, 13.4)	16.8 (8.1, 25.5)	8.3 (0.0, 17.4)	22.0 (12.2, 31.9)	
6 Months (95% CI)	- (-, -)	24.3 (14.2, 34.4)	14.7 (2.7, 26.7)	28.0 (17.3, 38.7)	
9 Months (95% CI)	- (-, -)	- (-, -)	100 (100, 100)	- (-, -)	
12 Months (95% CI)	- (-, -)	- (-, -)	100 (100, 100)	- (-, -)	
Hazard Ratio (95% CI) [1]		4.344 (1.003, 18.807)		1.847 (0.737, 4.634)	
p-value		0.0495		0.1908	

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-tte-itt-subgrp-a.sas Date: 15:03/05SEP2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Table 35.3.1.16.6.1.7a
Time to Onset of Oedema CMQ by Prior Cytoreductive Therapy
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Yes		No		
	Placebo (N=7)	Avapritinib 25 mg (N=19)	Placebo (N=64)	Avapritinib 25 mg (N=122)	P-Value [2]
Patients with Events (n (%))	0	5 (26.3)	8 (12.5)	31 (25.4)	NA
Patients Censored (n (%))	7 (100)	14 (73.7)	56 (87.5)	91 (74.6)	
Kaplan-Meier Estimates (Months)					
Median (95% CI)	- (-, -)	- (-, -)	6.34 (-, -)	- (-, -)	
25th, 75th percentiles	-, -	5.52, -	6.34, 6.34	5.22, -	
Min, Max	3.88*, 6.21*	0.92, 6.11*	0.10, 6.34	0.03, 6.51*	
3 Months (95% CI)	0.0 (0.0, 0.0)	15.8 (0.0, 32.2)	7.8 (1.2, 14.4)	19.9 (12.7, 27.0)	
6 Months (95% CI)	0.0 (0.0, 0.0)	28.0 (6.9, 49.0)	11.4 (3.4, 19.5)	25.7 (17.9, 33.6)	
9 Months (95% CI)	- (-, -)	- (-, -)	100 (100, 100)	- (-, -)	
12 Months (95% CI)	- (-, -)	- (-, -)	100 (100, 100)	- (-, -)	
Hazard Ratio (95% CI) [1]		- (-, -)		2.164 (0.995, 4.709)	
p-value		NA		0.0516	

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-tte-itt-subgrp-a.sas Date: 15:03/05SEP2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

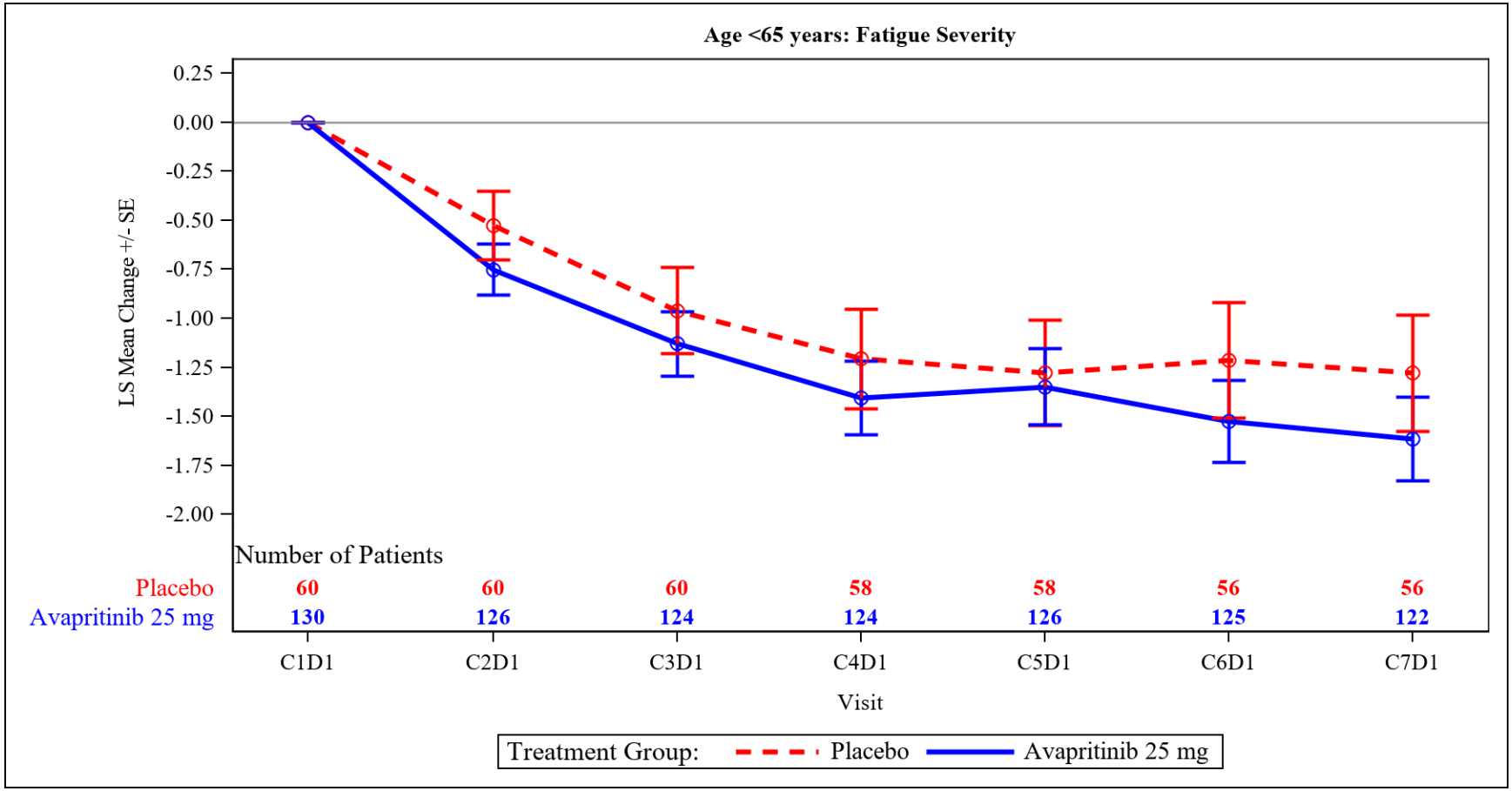
Table 35.3.1.16.6.1.8a
Time to Onset of Oedema CMQ by Baseline Opioid Use
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

	Yes		No		
	Placebo (N=11)	Avapritinib 25 mg (N=26)	Placebo (N=60)	Avapritinib 25 mg (N=115)	P-Value [2]
Patients with Events (n (%))	2 (18.2)	6 (23.1)	6 (10.0)	30 (26.1)	0.548
Patients Censored (n (%))	9 (81.8)	20 (76.9)	54 (90.0)	85 (73.9)	
Kaplan-Meier Estimates (Months)					
Median (95% CI)	6.34 (-, -)	- (-, -)	- (-, -)	- (-, -)	
25th, 75th percentiles	6.34, 6.34	-, -	-, -	5.22, -	
Min, Max	0.85, 6.34	0.26, 6.51*	0.10, 6.28*	0.03, 6.41*	
3 Months (95% CI)	9.1 (0.0, 26.1)	24.1 (7.3, 41.0)	6.7 (0.4, 13.0)	18.4 (11.3, 25.4)	
6 Months (95% CI)	9.1 (0.0, 26.1)	24.1 (7.3, 41.0)	10.6 (2.5, 18.6)	26.5 (18.3, 34.6)	
9 Months (95% CI)	100 (100, 100)	- (-, -)	- (-, -)	- (-, -)	
12 Months (95% CI)	100 (100, 100)	- (-, -)	- (-, -)	- (-, -)	
Hazard Ratio (95% CI) [1]		1.525 (0.303, 7.660)		2.775 (1.155, 6.668)	
p-value		0.6087		0.0225	

Abbreviations: CMQ = Customized MedDRA Queries.
Note: * = censored observation.
Notes: Time to first onset of Oedema CMQ is defined as from day 1 of avapritinib/placebo to the first Oedema CMQ start date. For patients without Oedema CMQ, time to first onset will be censored at the minimum of date of last study drug dose + 30 days, cutoff date, death date, or end of study date.
[1] Hazard Ratio is calculated based on Cox proportional hazards model. HR < 1 suggests that Avapritinib experiences a lower event probability during a unit of time than placebo.
[2] Two-sided p-values for treatment-by-subgroup interaction are from Cox proportional hazards model with treatment, subgroup, treatment*subgroup in the model.
Cross References: Listing 16.2.6.1
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/t-ae-cmq-tte-itt-subgrp-a.sas Date: 15:03/05SEP2023

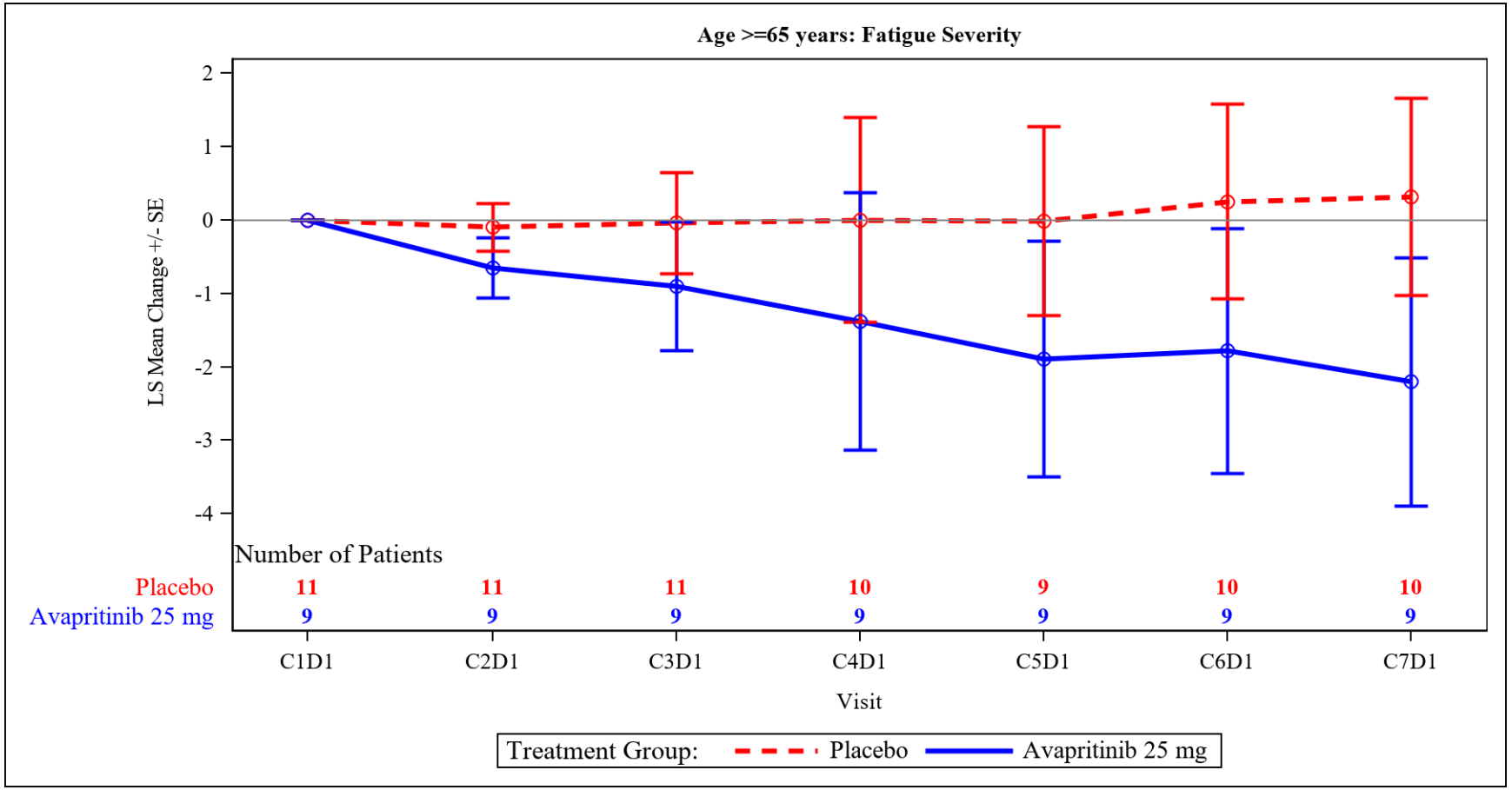
Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Figure 35.2.2.3.1.1a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Intent-to-Treat Population , Part 2 (Part 2 Baseline)



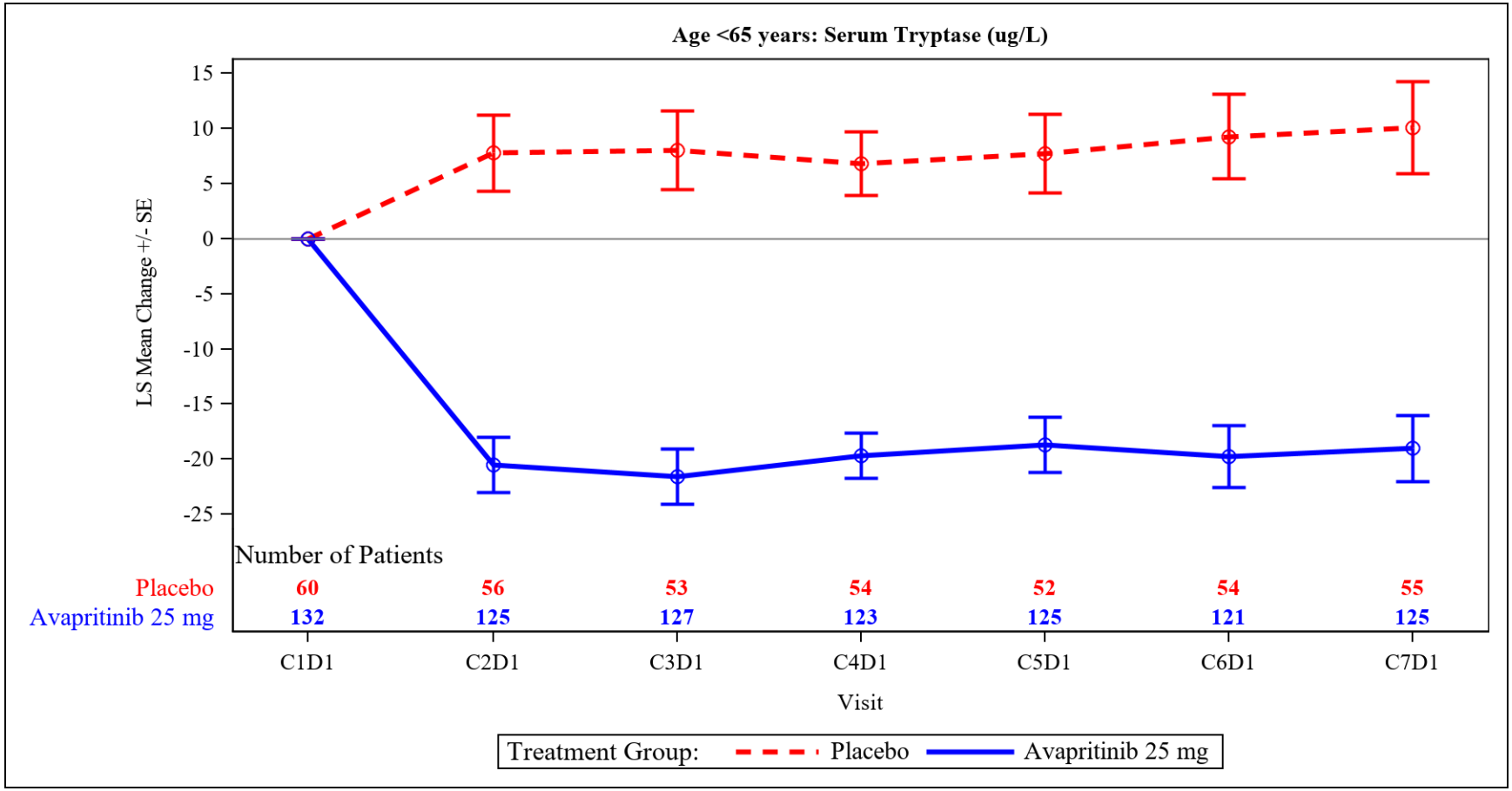
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-ismsaf-ind-sum-g-itt-age-a.sas Date: 16:20/07AUG2023

Figure 35.2.2.3.1.1a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Age Group
Intent-to-Treat Population , Part 2 (Part 2 Baseline)



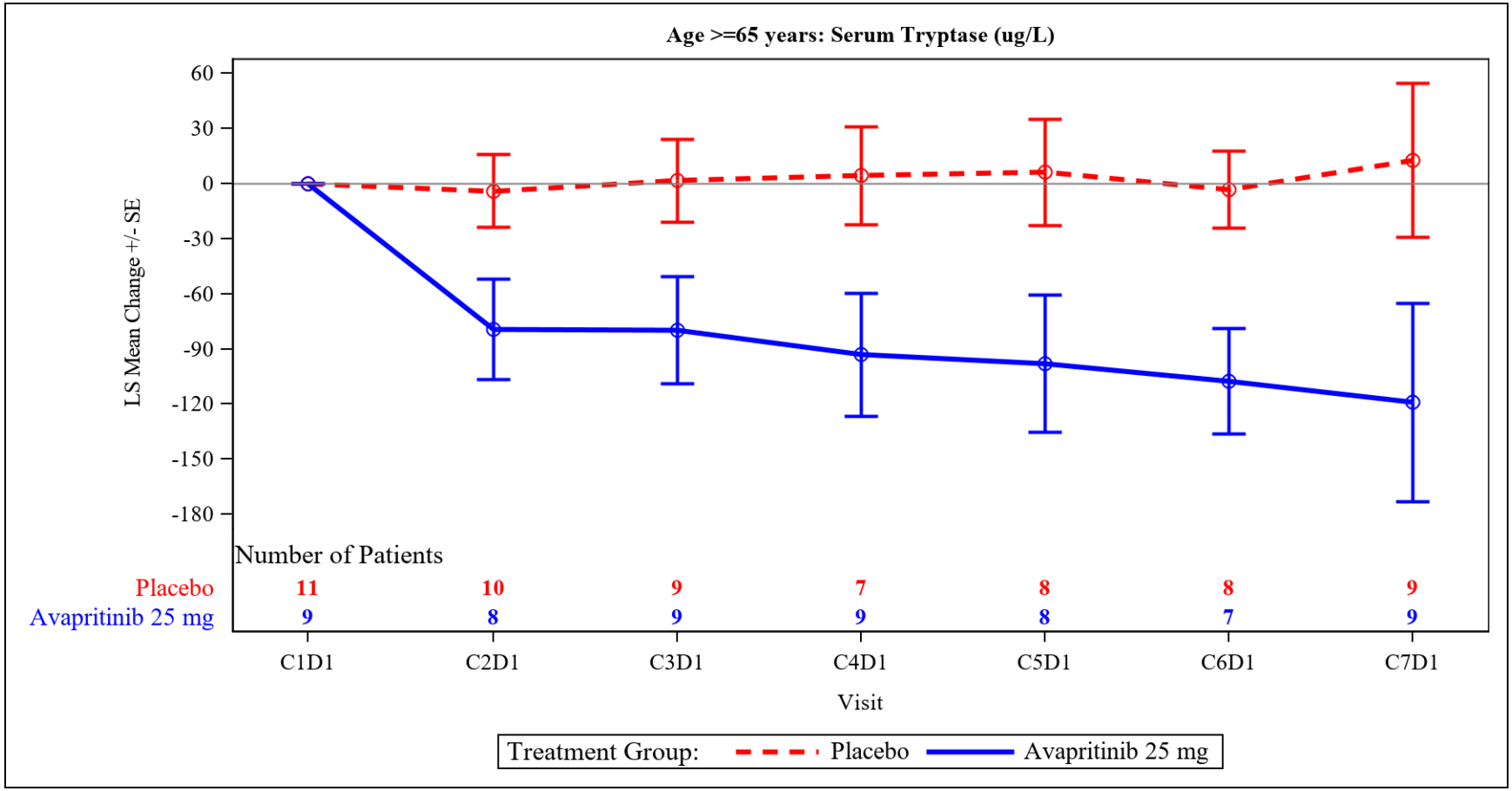
Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Figure 35.2.3.2.1.1a
LSMean Plot of Change from Baseline in Serum Tryptase (ng/mL) by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)



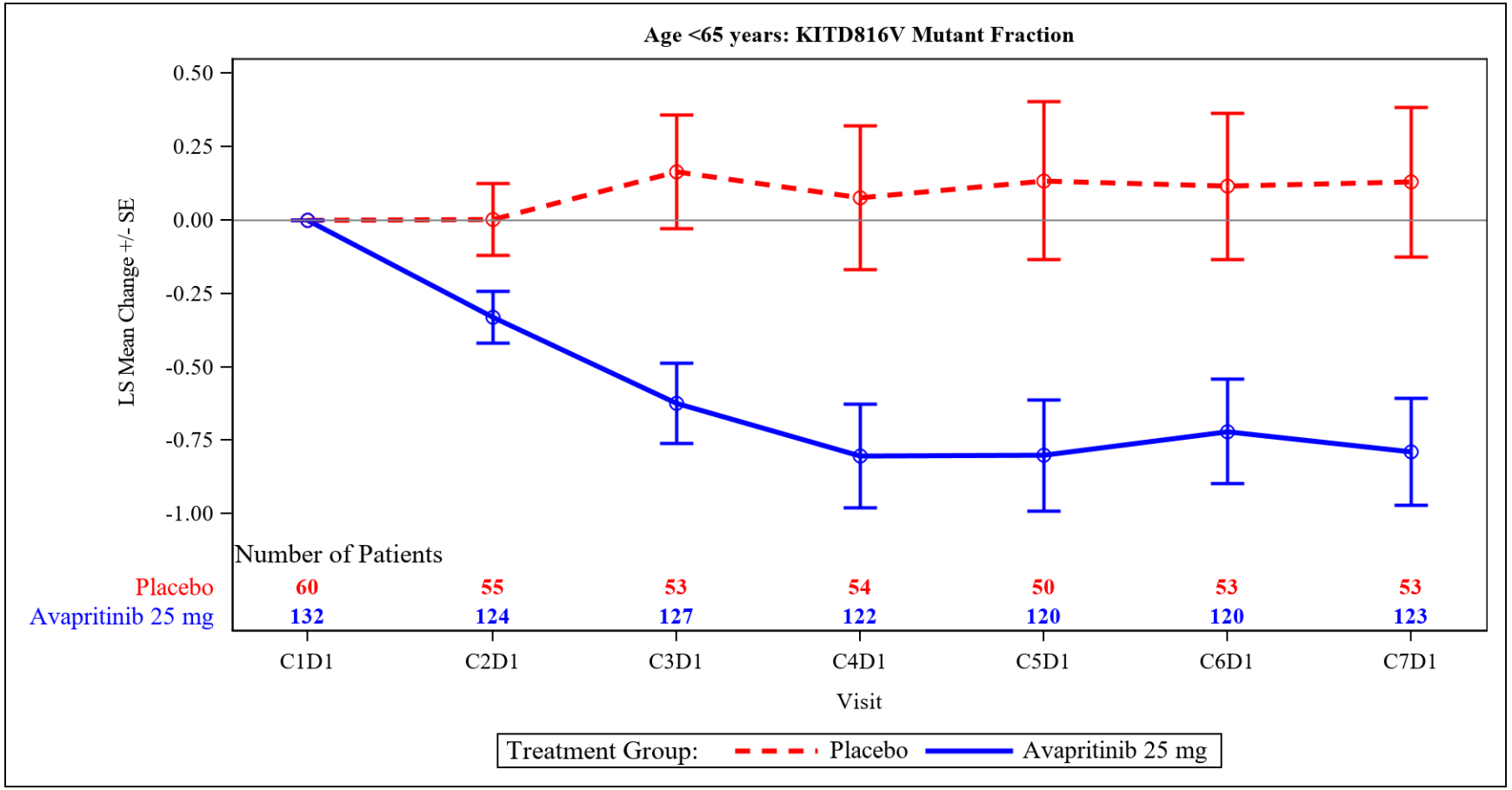
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-tryp-sum-g-itt-age-a.sas Date: 16:29/07AUG2023

Figure 35.2.3.2.1.1a
LSMean Plot of Change from Baseline in Serum Tryptase (ng/mL) by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)



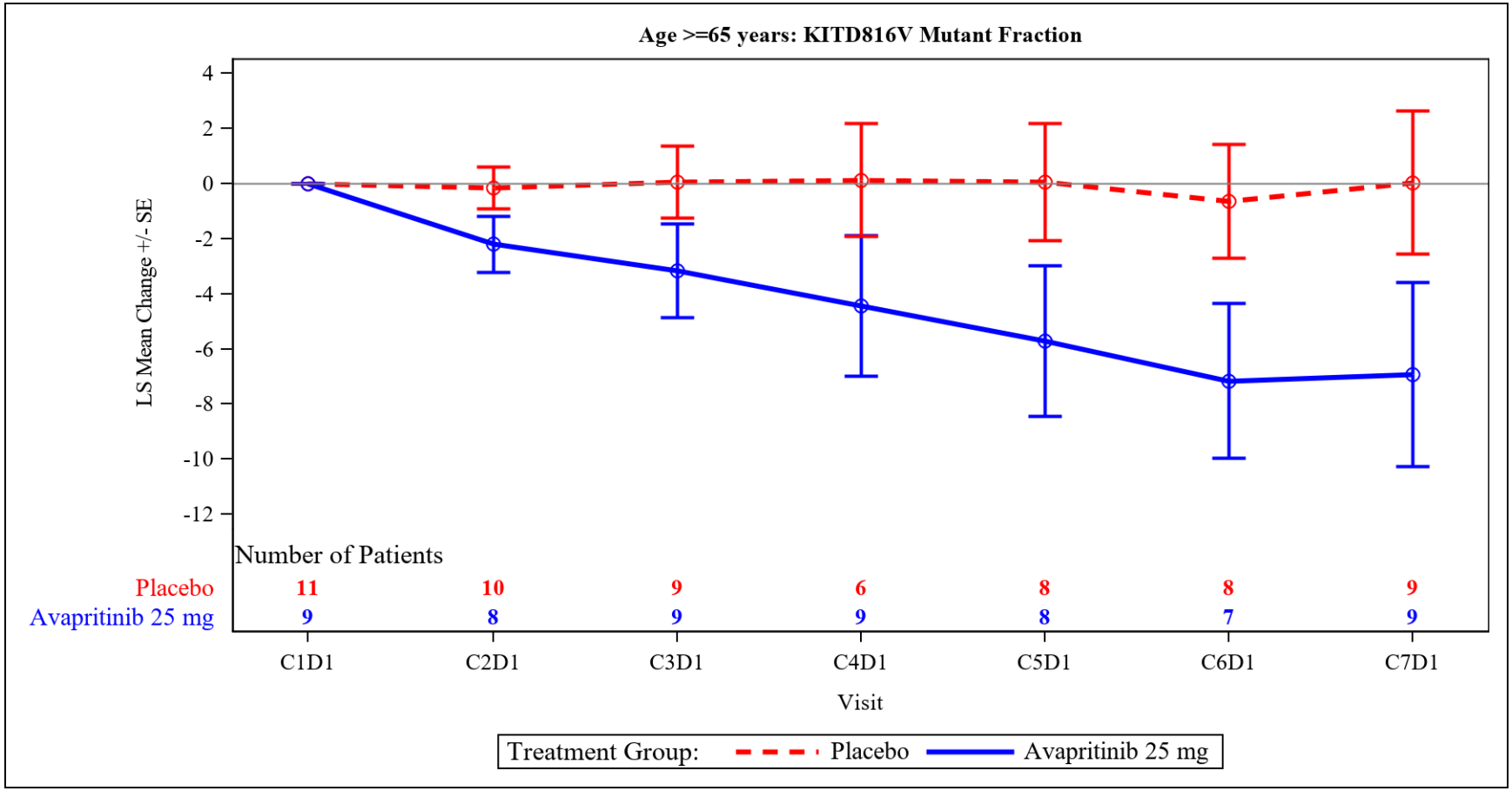
Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Figure 35.2.4.1.1.1a
LSMean Plot of Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-mut-sum-g-itt-age-a.sas Date: 16:30/07AUG2023

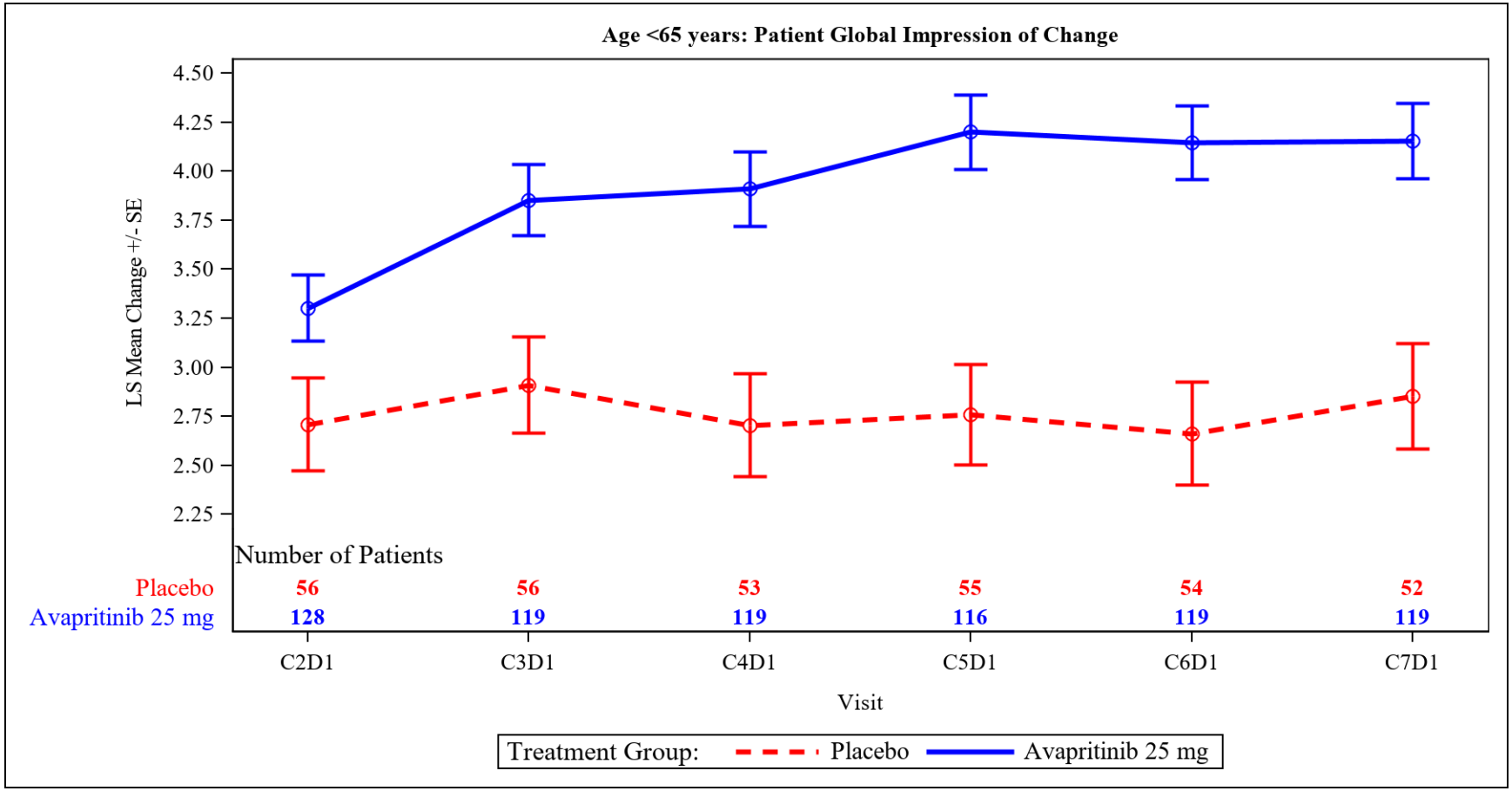
Figure 35.2.4.1.1.1a
LSMean Plot of Change from Baseline in KIT D816V Mutation Allele Fraction in Blood by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-mut-sum-g-itt-age-a.sas Date: 16:30/07AUG2023

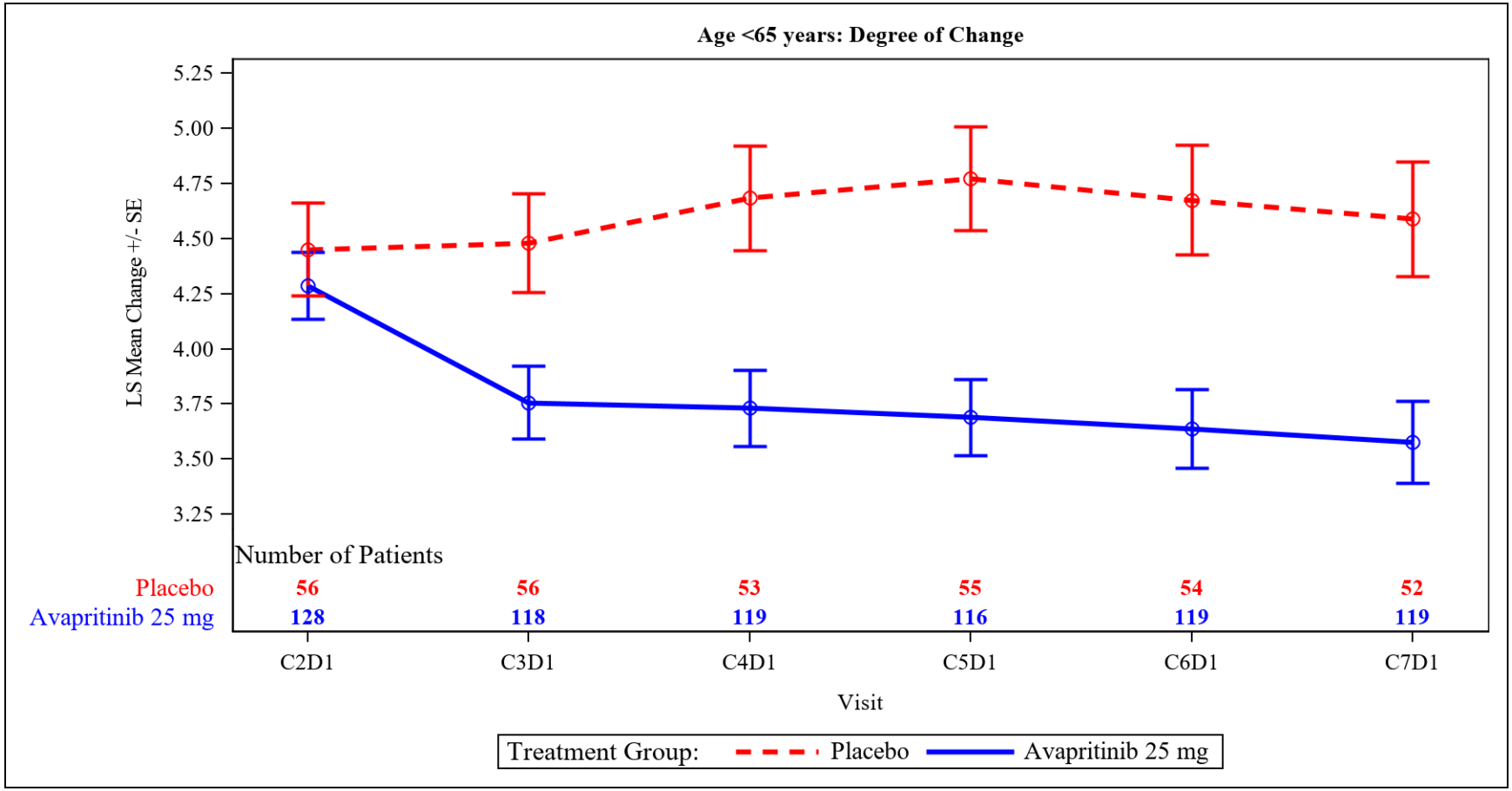
Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Figure 35.2.7.1.1a
LSMean Plot of PGIC by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)



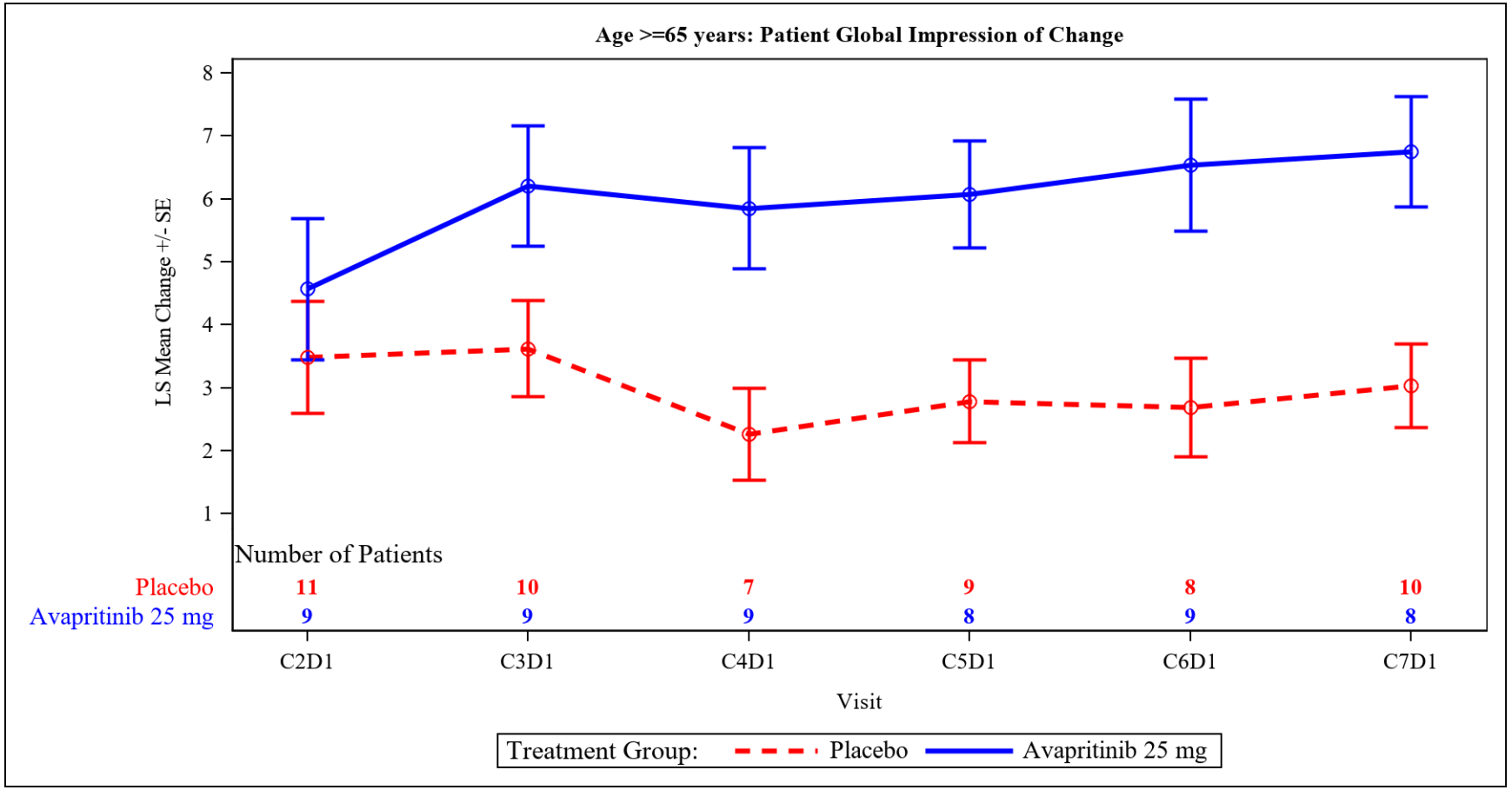
Patient Global Impression of Change Scale: 1=No change, 2=Almost the same, 3=A little better, 4=Somewhat better, 5=Moderately Better, 6=Better, 7=A great deal better.
Degree of Change is in the range of 0 to 10, with 0 = much better and 10 = much worse.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-pgic-sum-g-itt-age-a.sas Date: 16:30/07AUG2023

Figure 35.2.7.1.1a
LSMean Plot of PGIC by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)



Patient Global Impression of Change Scale: 1=No change, 2=Almost the same, 3=A little better, 4=Somewhat better, 5=Moderately Better, 6=Better, 7=A great deal better.
Degree of Change is in the range of 0 to 10, with 0 = much better and 10 = much worse.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-pgic-sum-g-itt-age-a.sas Date: 16:30/07AUG2023

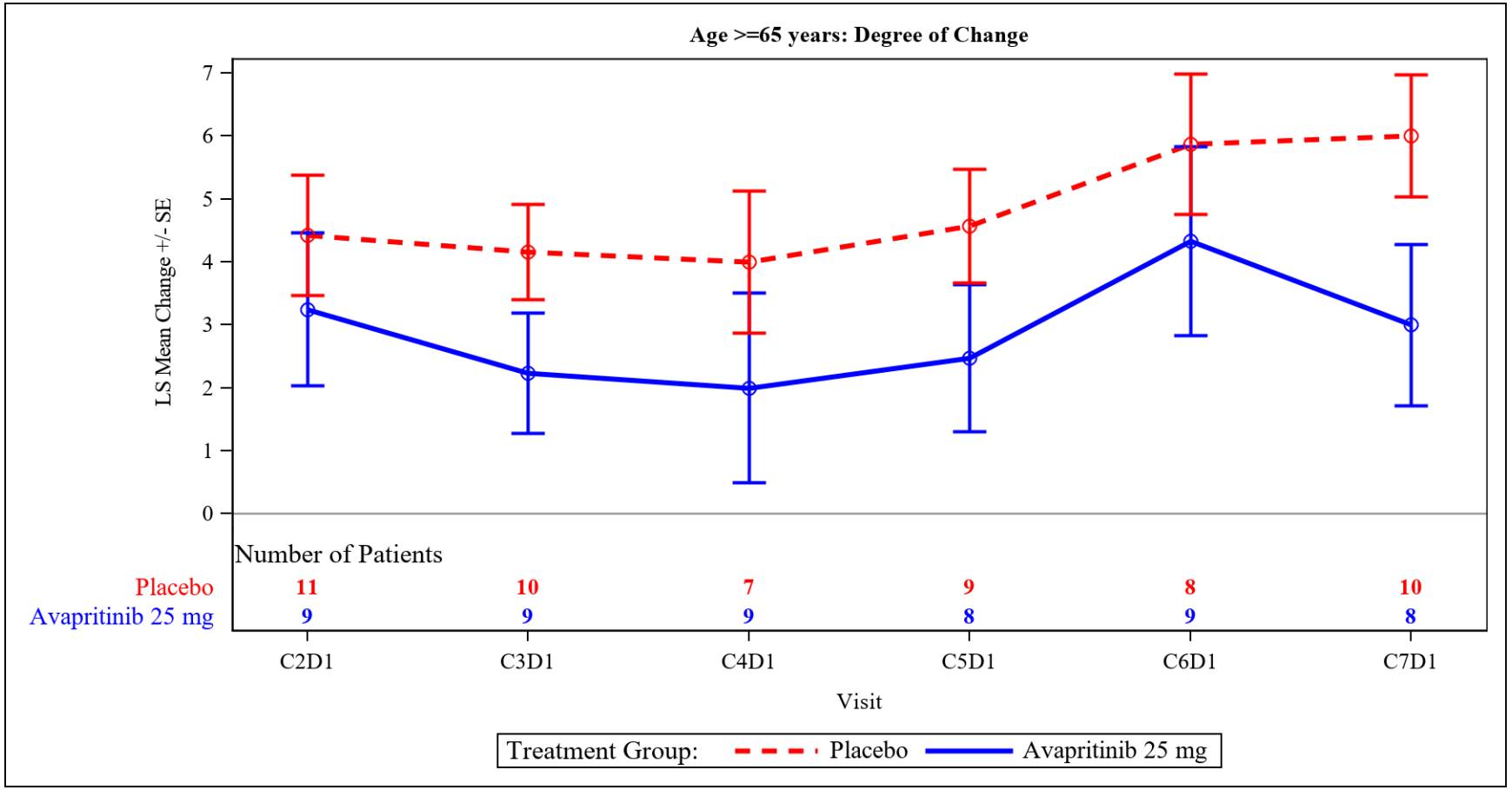
Figure 35.2.7.1.1a
LSMean Plot of PGIC by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)



Patient Global Impression of Change Scale: 1=No change, 2=Almost the same, 3=A little better, 4=Somewhat better, 5=Moderately Better, 6=Better, 7=A great deal better.
Degree of Change is in the range of 0 to 10, with 0 = much better and 10 = much worse.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-pgic-sum-g-itt-age-a.sas Date: 16:30/07AUG2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

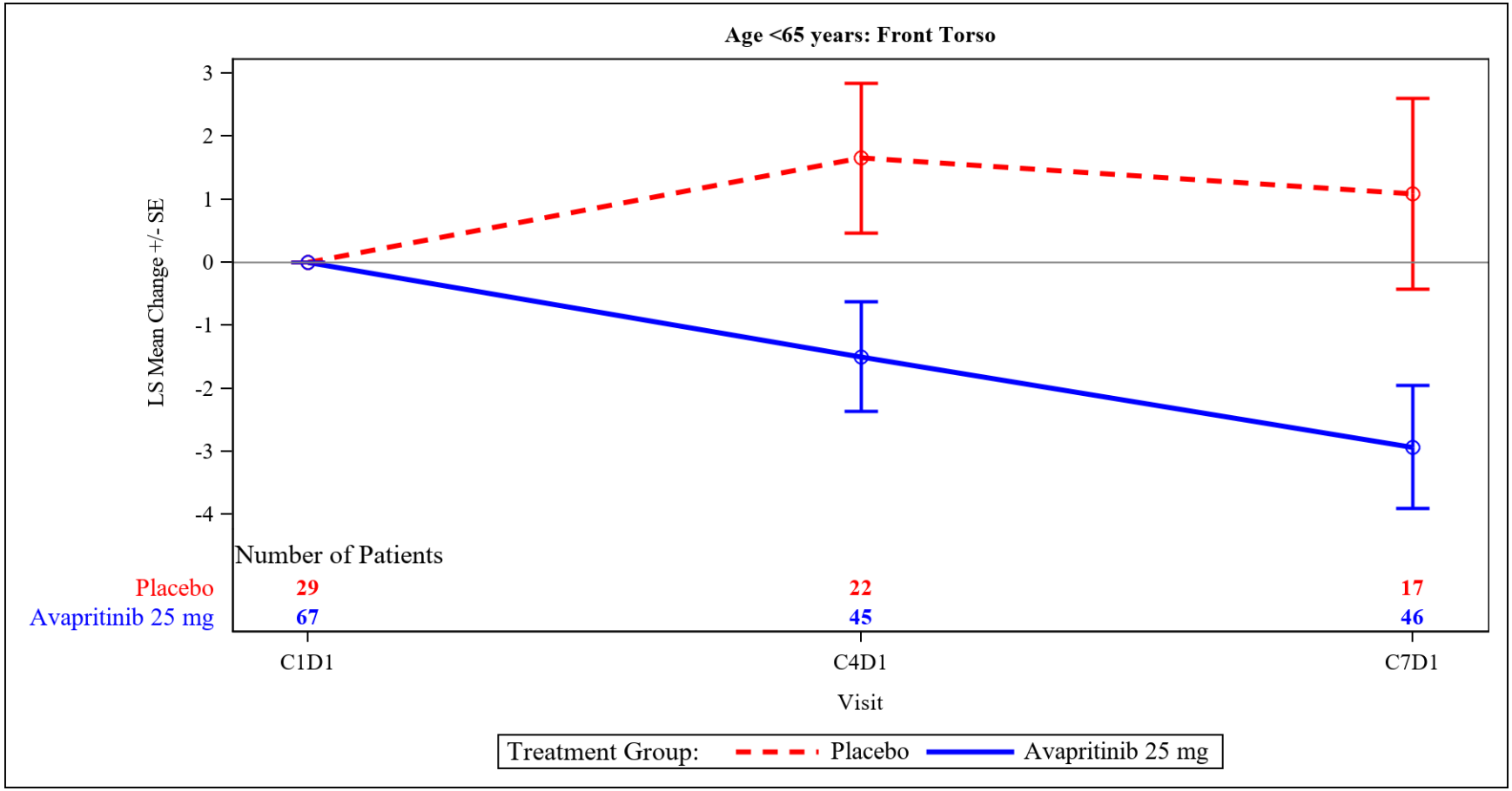
Figure 35.2.7.1.1a
LSMean Plot of PGIC by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)



Patient Global Impression of Change Scale: 1=No change, 2=Almost the same, 3=A little better, 4=Somewhat better, 5=Moderately Better, 6=Better, 7=A great deal better.
Degree of Change is in the range of 0 to 10, with 0 = much better and 10 = much worse.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-pgic-sum-g-itt-age-a.sas Date: 16:30/07AUG2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Figure 35.2.11.4.1.1a
LSMean Plot of Mastocytosis in Skin by Age Group
Safety Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-mast-skin-g-saf-age-a.sas Date: 16:32/07AUG2023

Figure 35.2.11.4.1.1a
LSMean Plot of Mastocytosis in Skin by Age Group
Safety Population, Part 2 (Part 2 Baseline)

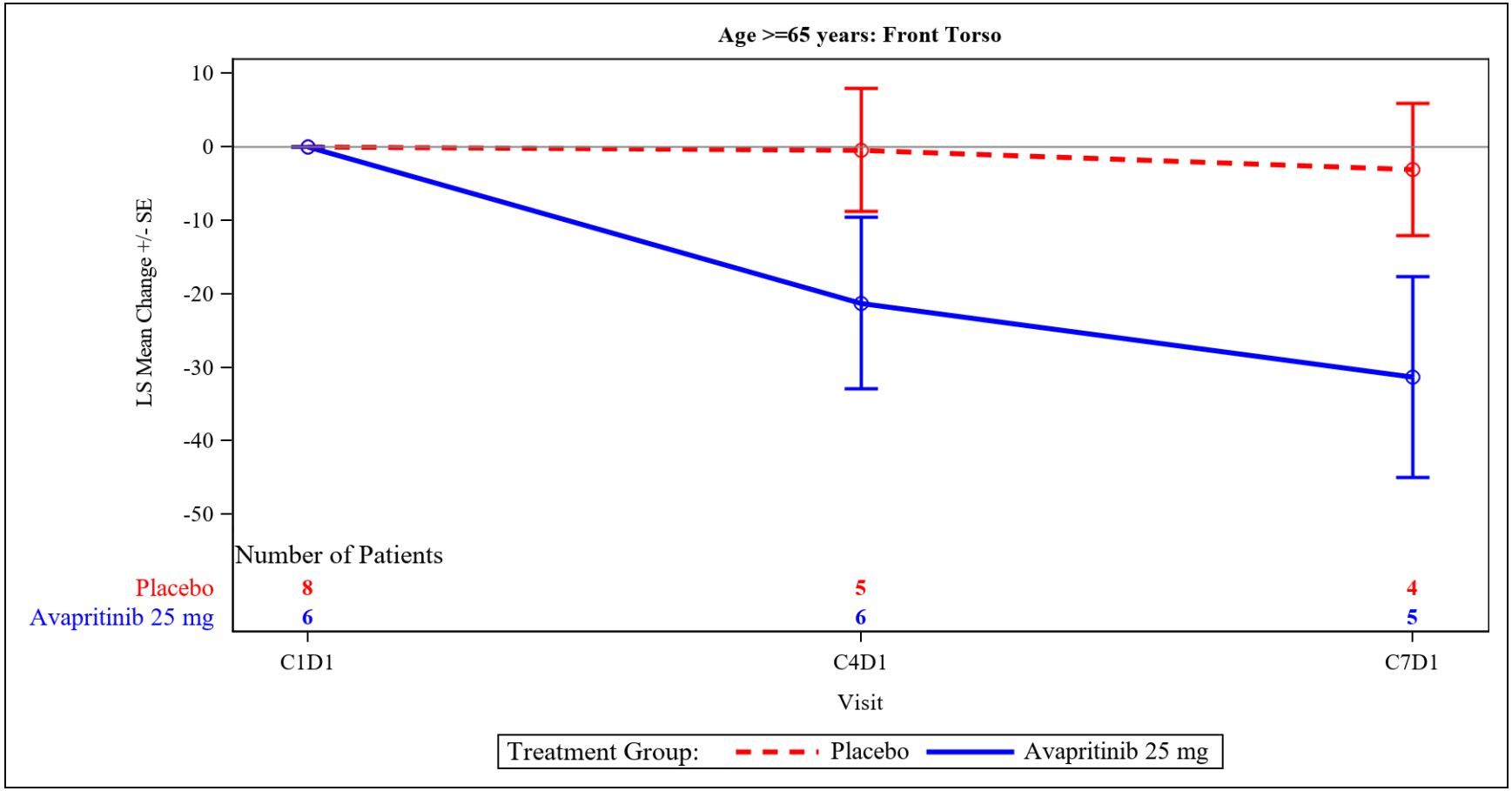
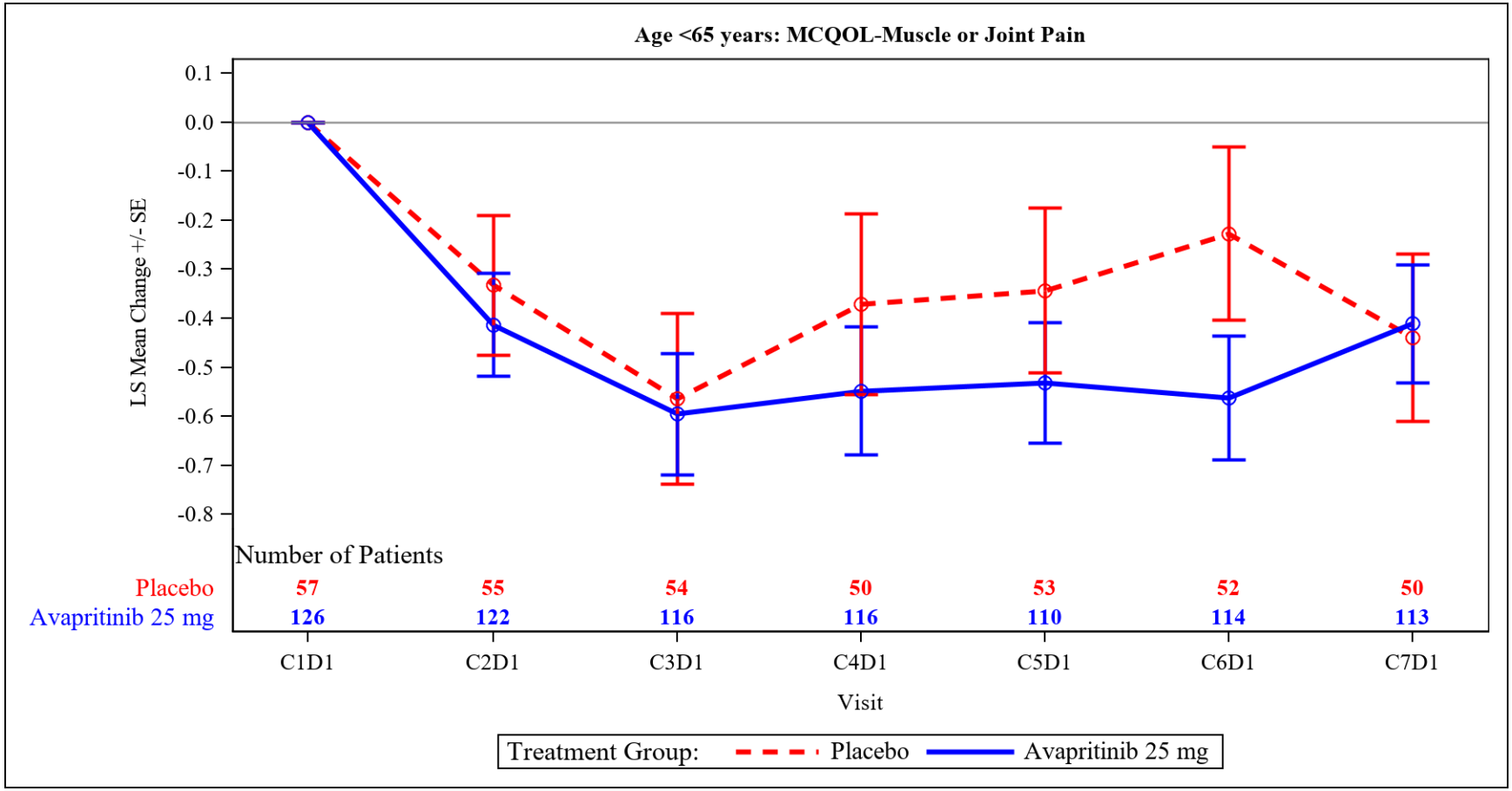


Figure 35.2.12.1.1a
LSMean Plot of Change from Baseline in Individual MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-mcqol-ind-g-itt-age-a.sas Date: 16:32/07AUG2023

Figure 35.2.12.1.1a
LSMean Plot of Change from Baseline in Individual MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

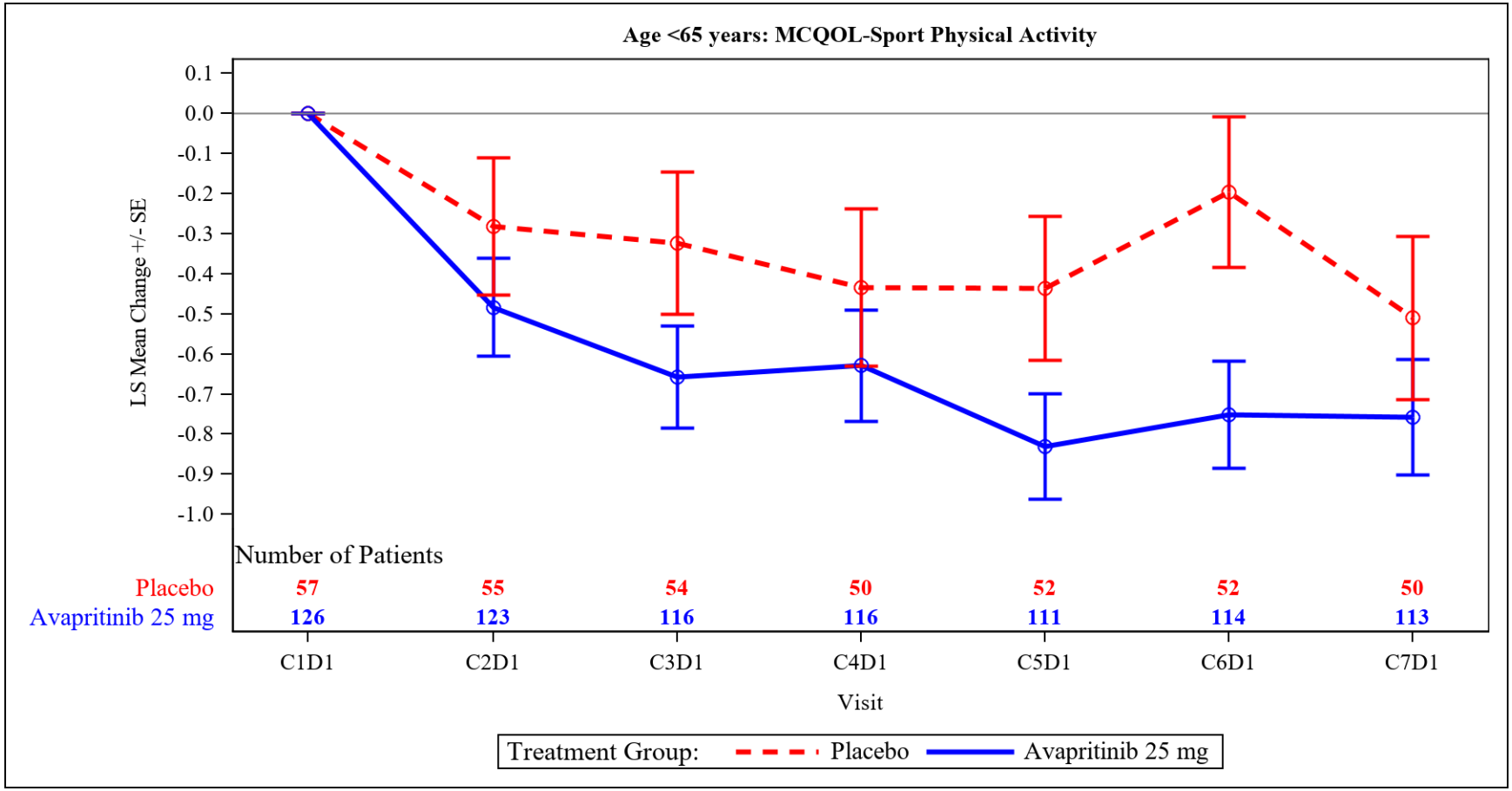


Figure 35.2.12.1.1a
LSMean Plot of Change from Baseline in Individual MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

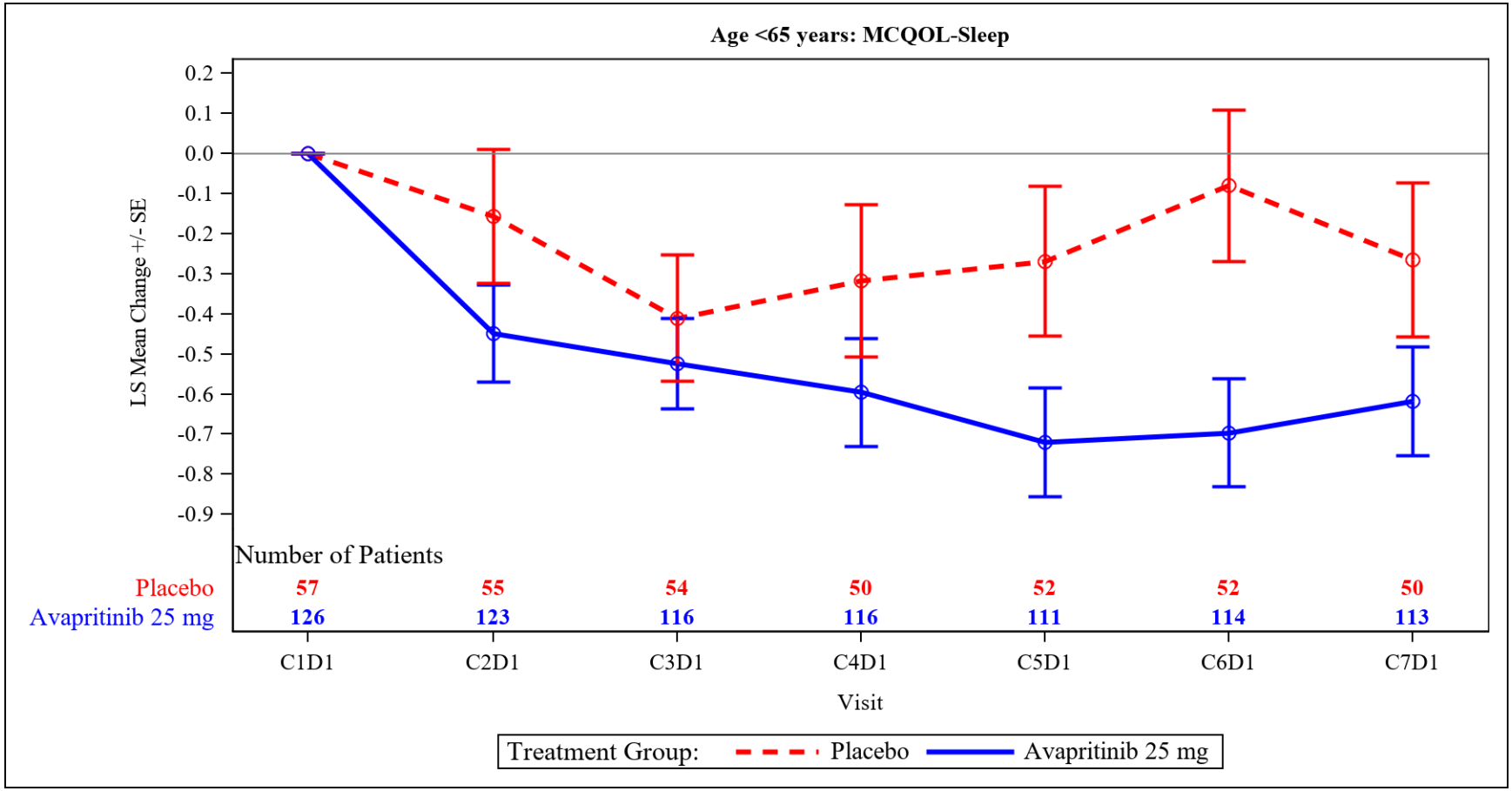
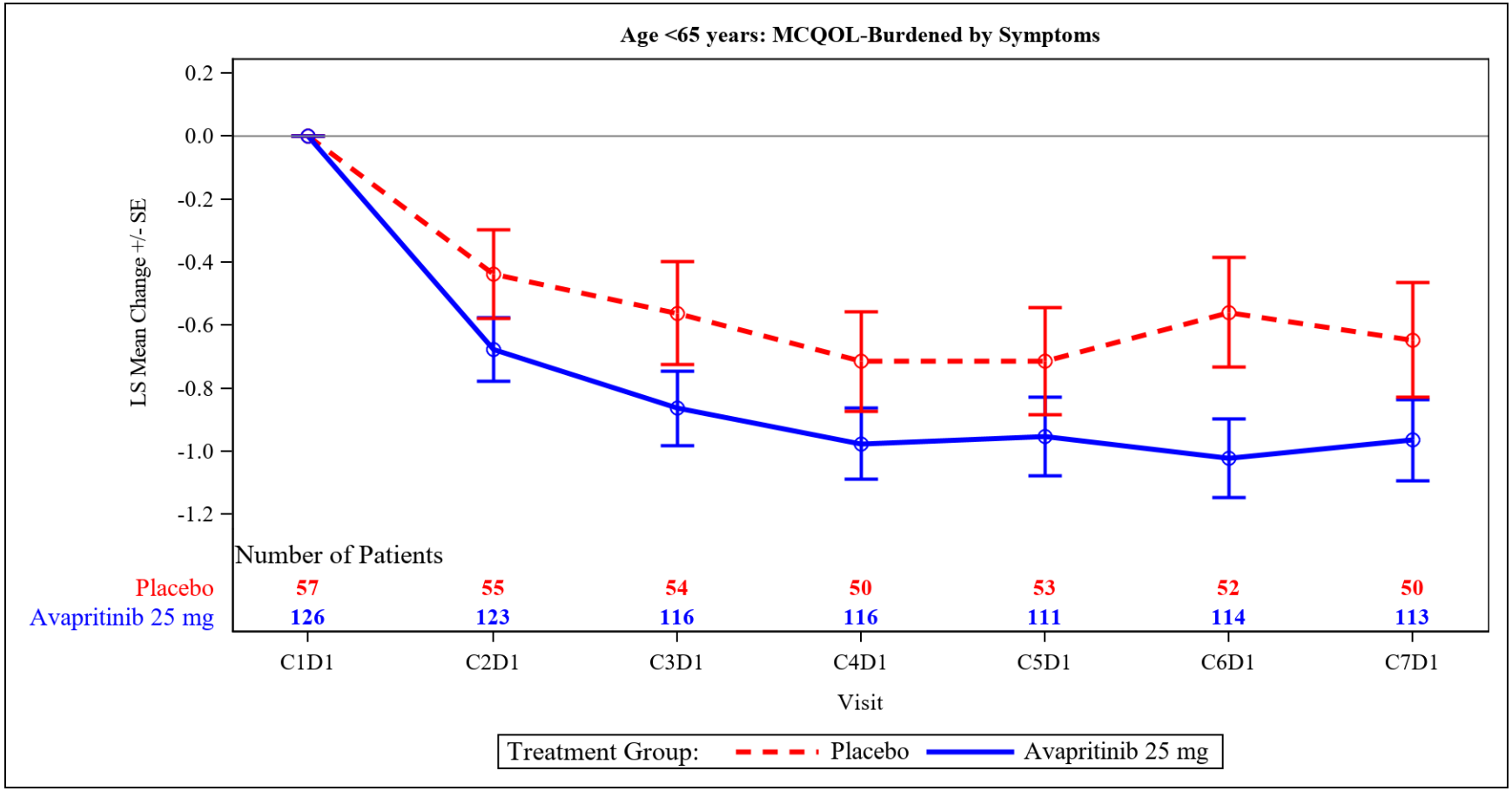


Figure 35.2.12.1.1a
LSMean Plot of Change from Baseline in Individual MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-mcqol-ind-g-itt-age-a.sas Date: 16:32/07AUG2023

Figure 35.2.12.1.1a
LSMean Plot of Change from Baseline in Individual MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

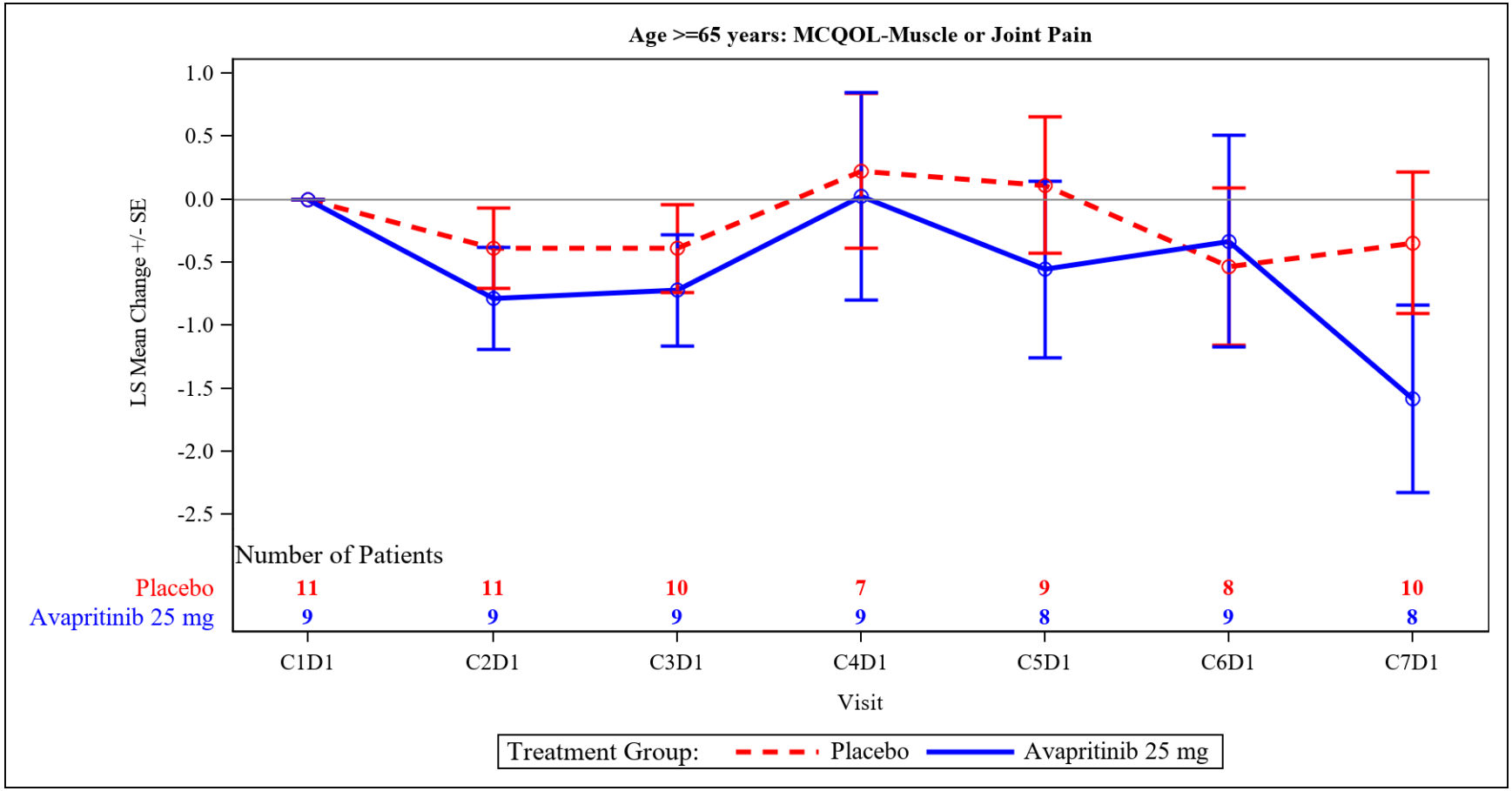


Figure 35.2.12.1.1a
LSMean Plot of Change from Baseline in Individual MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

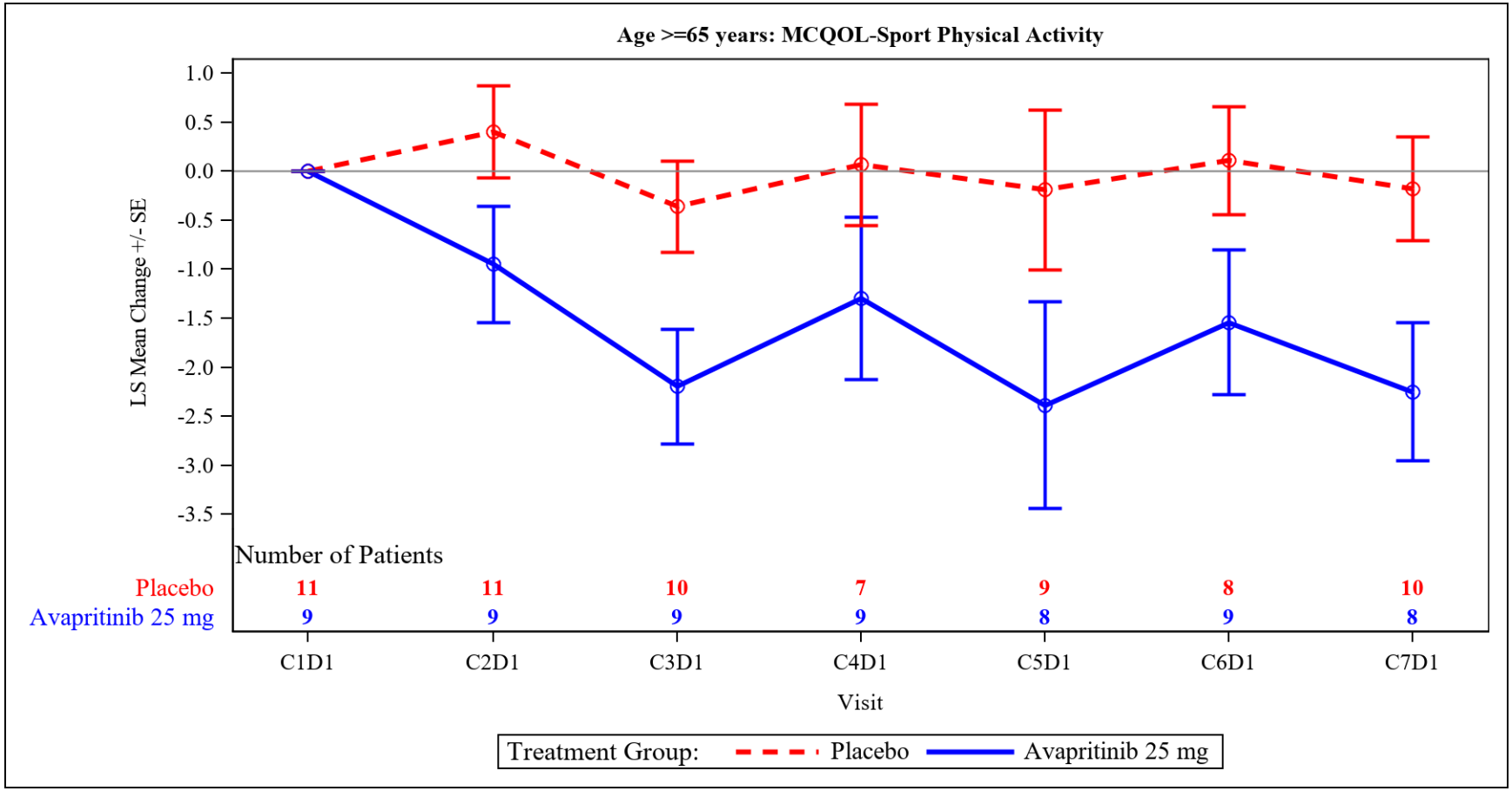


Figure 35.2.12.1.1a
LSMean Plot of Change from Baseline in Individual MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)

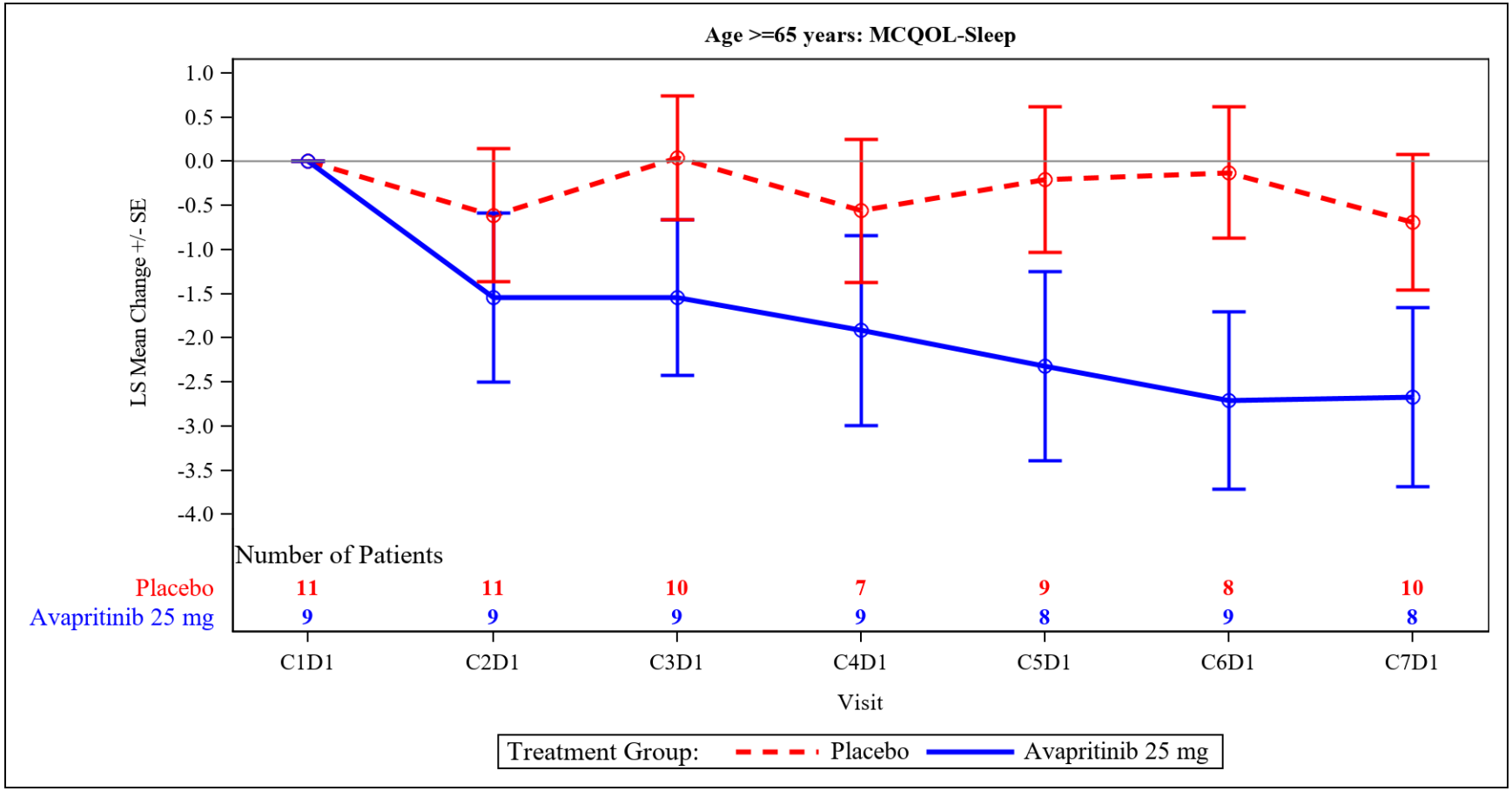
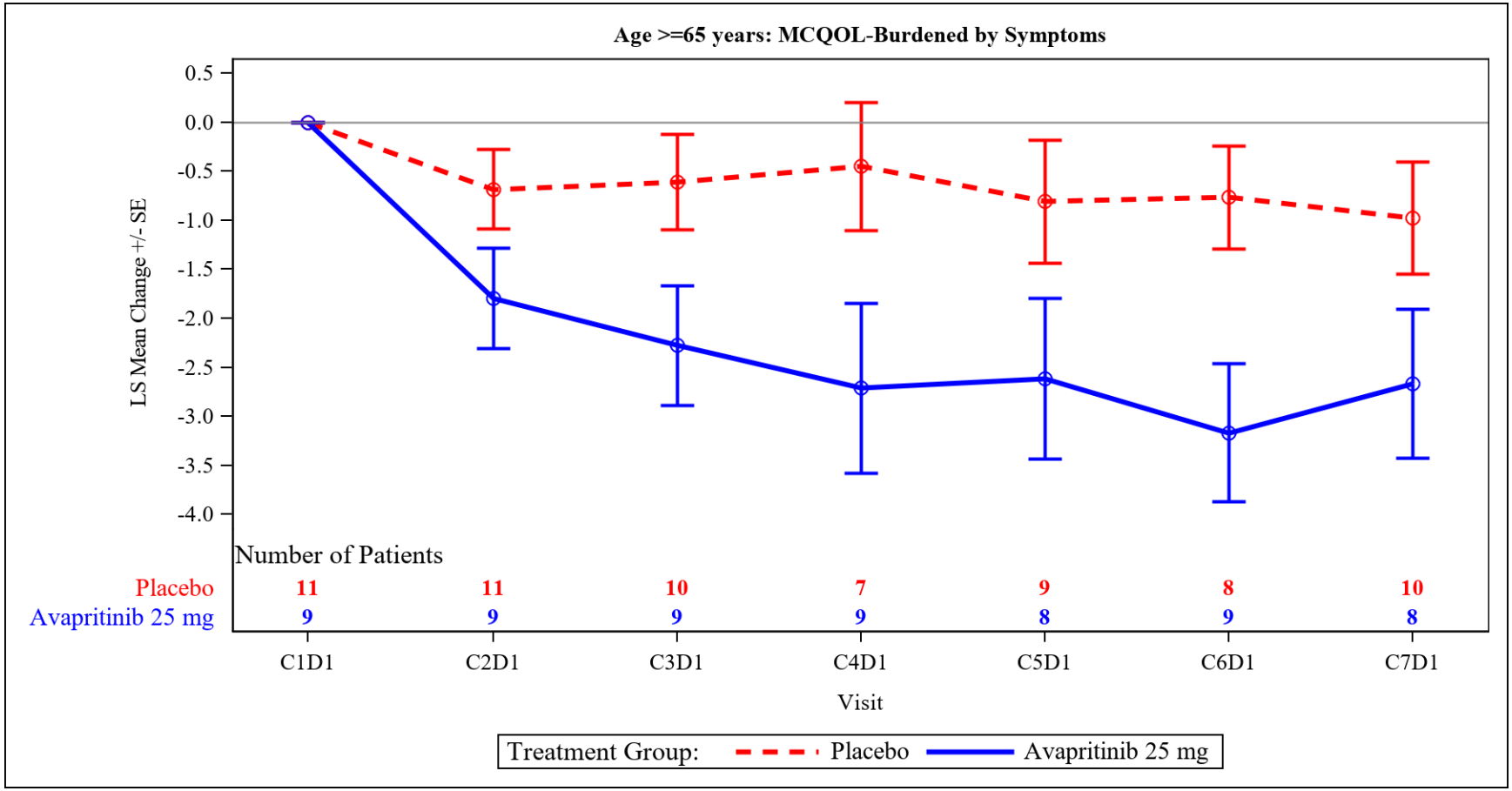


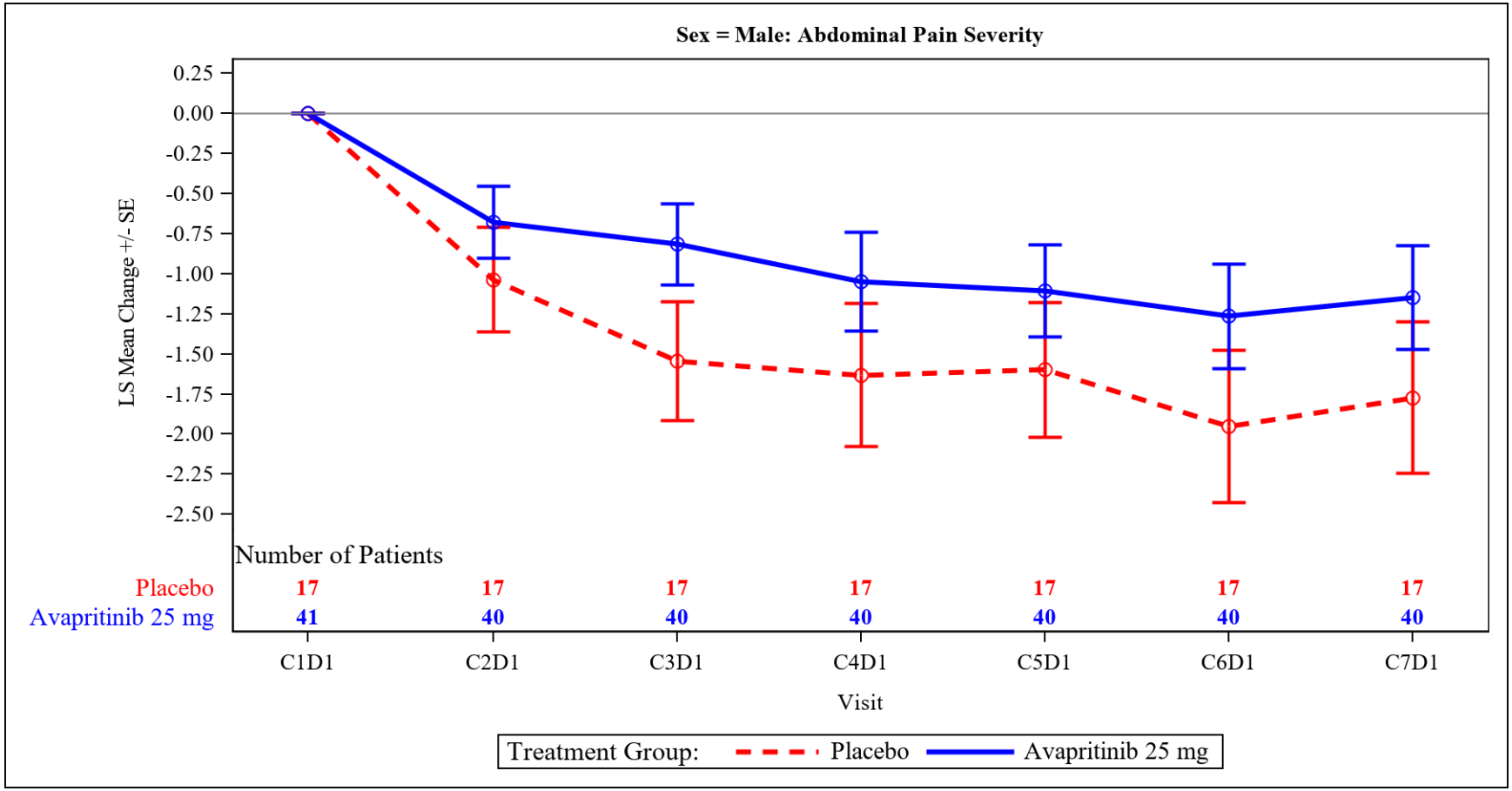
Figure 35.2.12.1.1a
LSMean Plot of Change from Baseline in Individual MC-QoL by Age Group
Intent-to-Treat Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-mcqol-ind-g-itt-age-a.sas Date: 16:32/07AUG2023

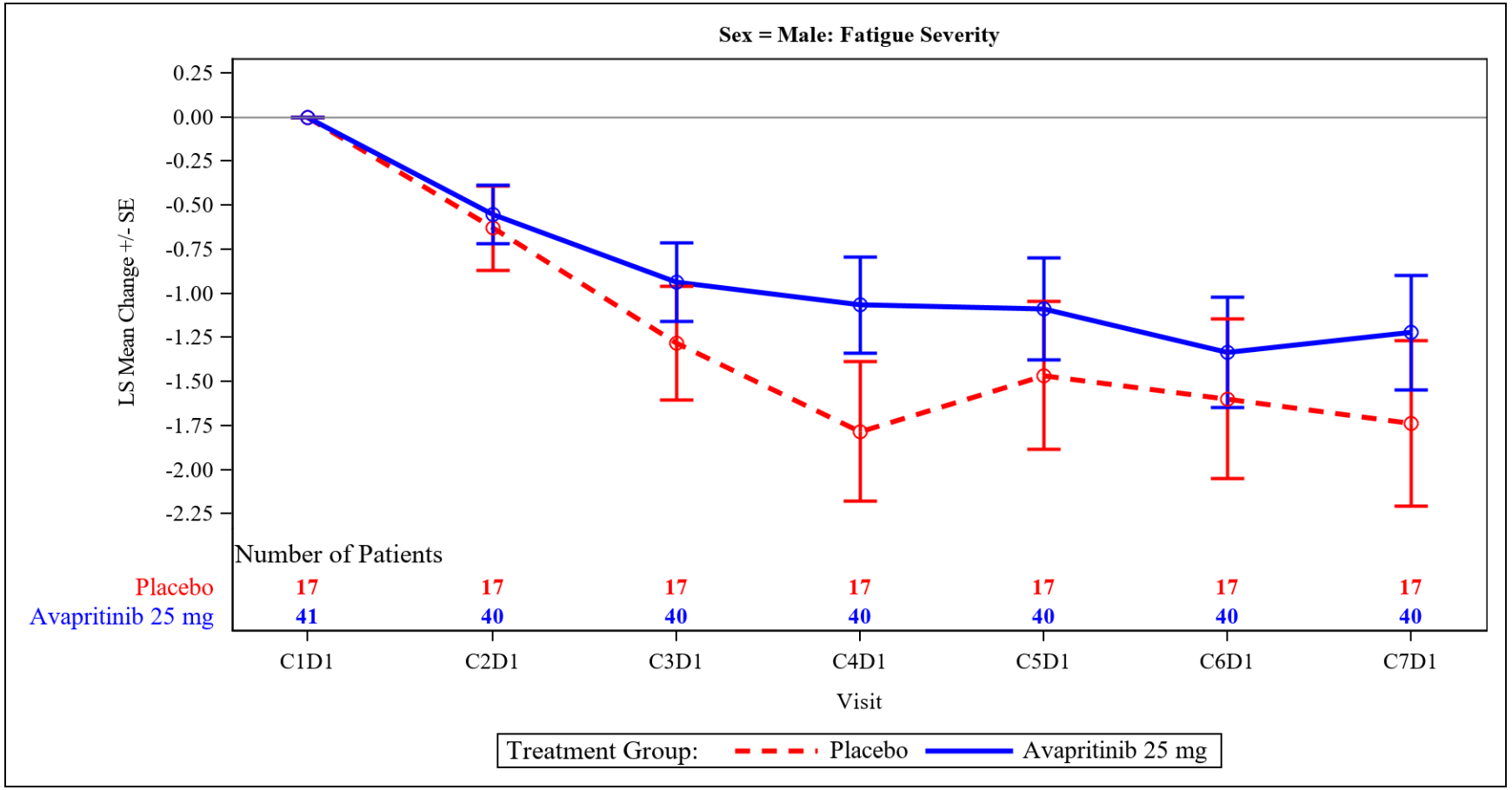
Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Figure 35.2.2.3.1.2a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Intent-to-Treat Population , Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-ismsaf-ind-sum-g-itt-sex-a.sas Date: 16:21/07AUG2023

Figure 35.2.2.3.1.2a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Intent-to-Treat Population , Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-ismsaf-ind-sum-g-itt-sex-a.sas Date: 16:21/07AUG2023

Figure 35.2.2.3.1.2a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

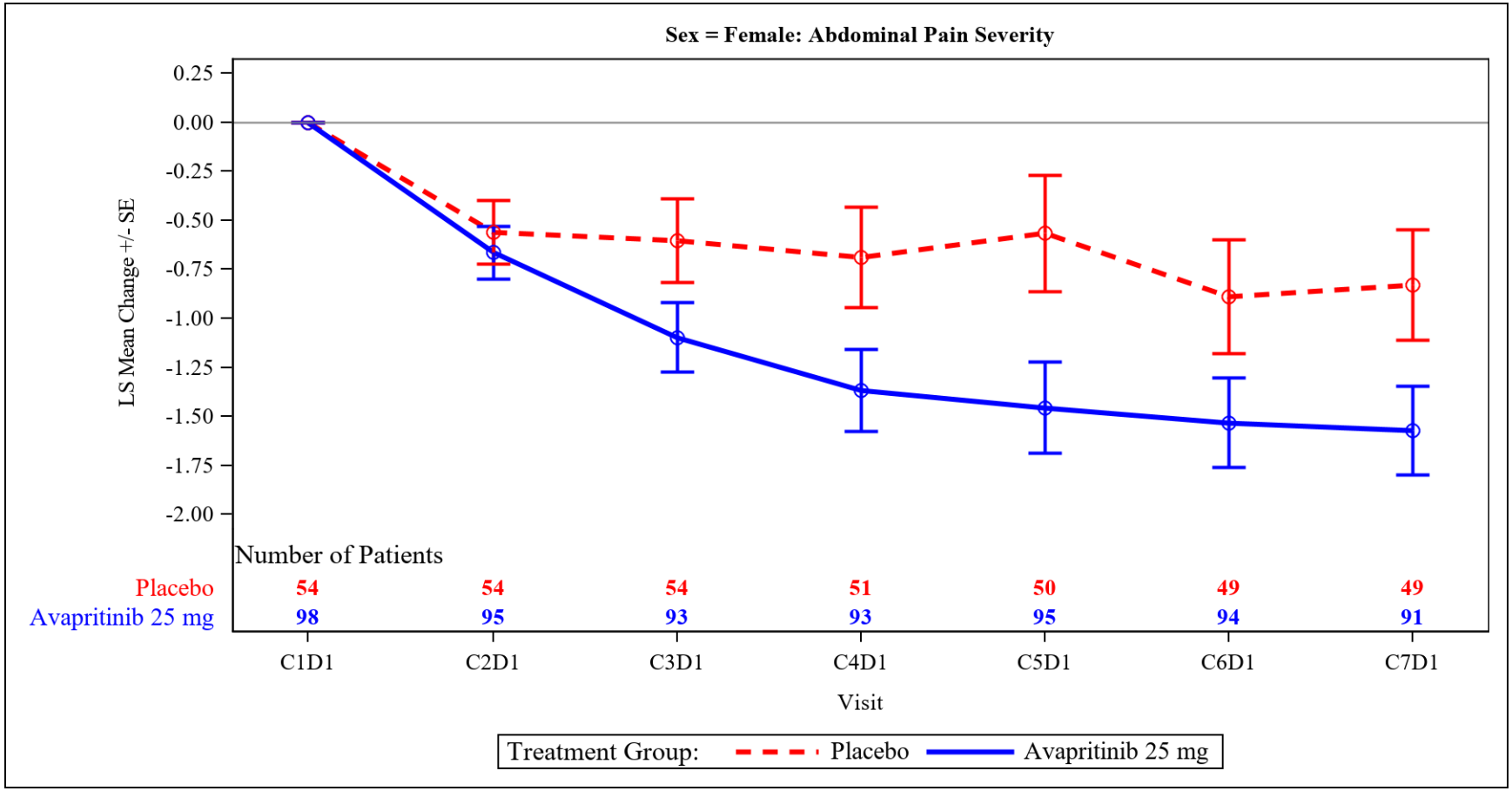
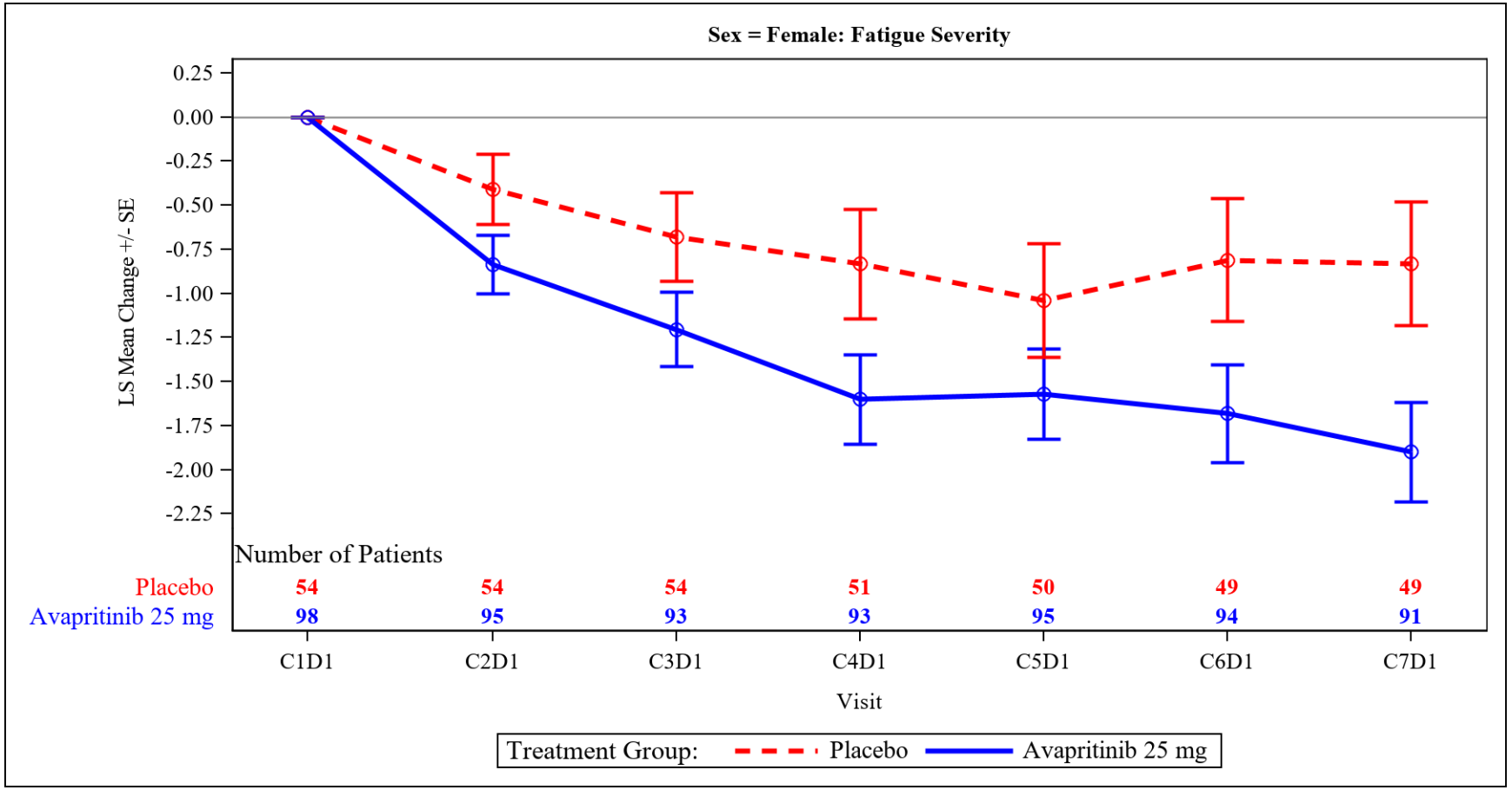


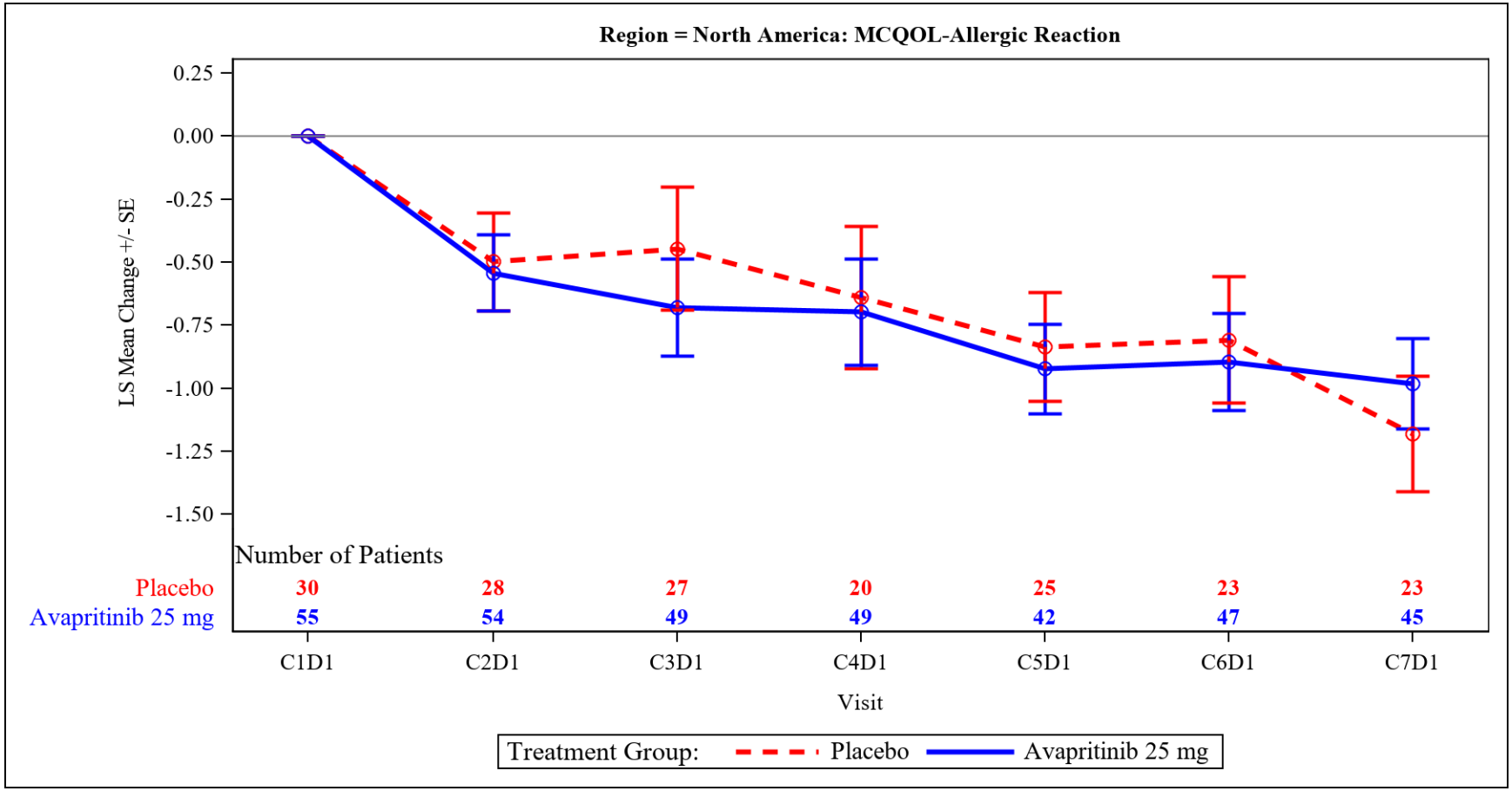
Figure 35.2.2.3.1.2a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Sex
Intent-to-Treat Population , Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-ismsaf-ind-sum-g-itt-sex-a.sas Date: 16:21/07AUG2023

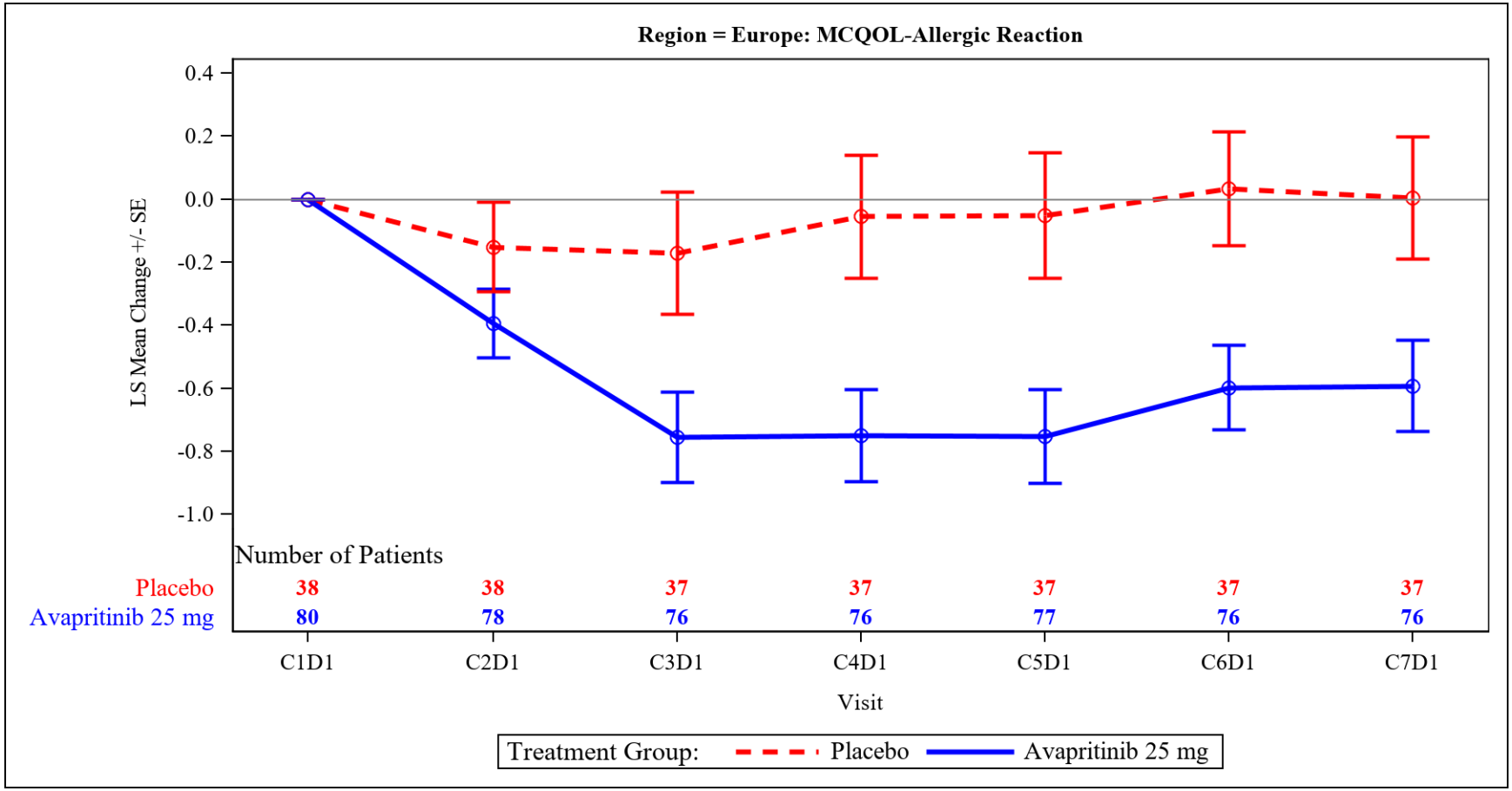
Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Figure 35.2.12.1.3a
LSMean Plot of Change from Baseline in Individual MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)



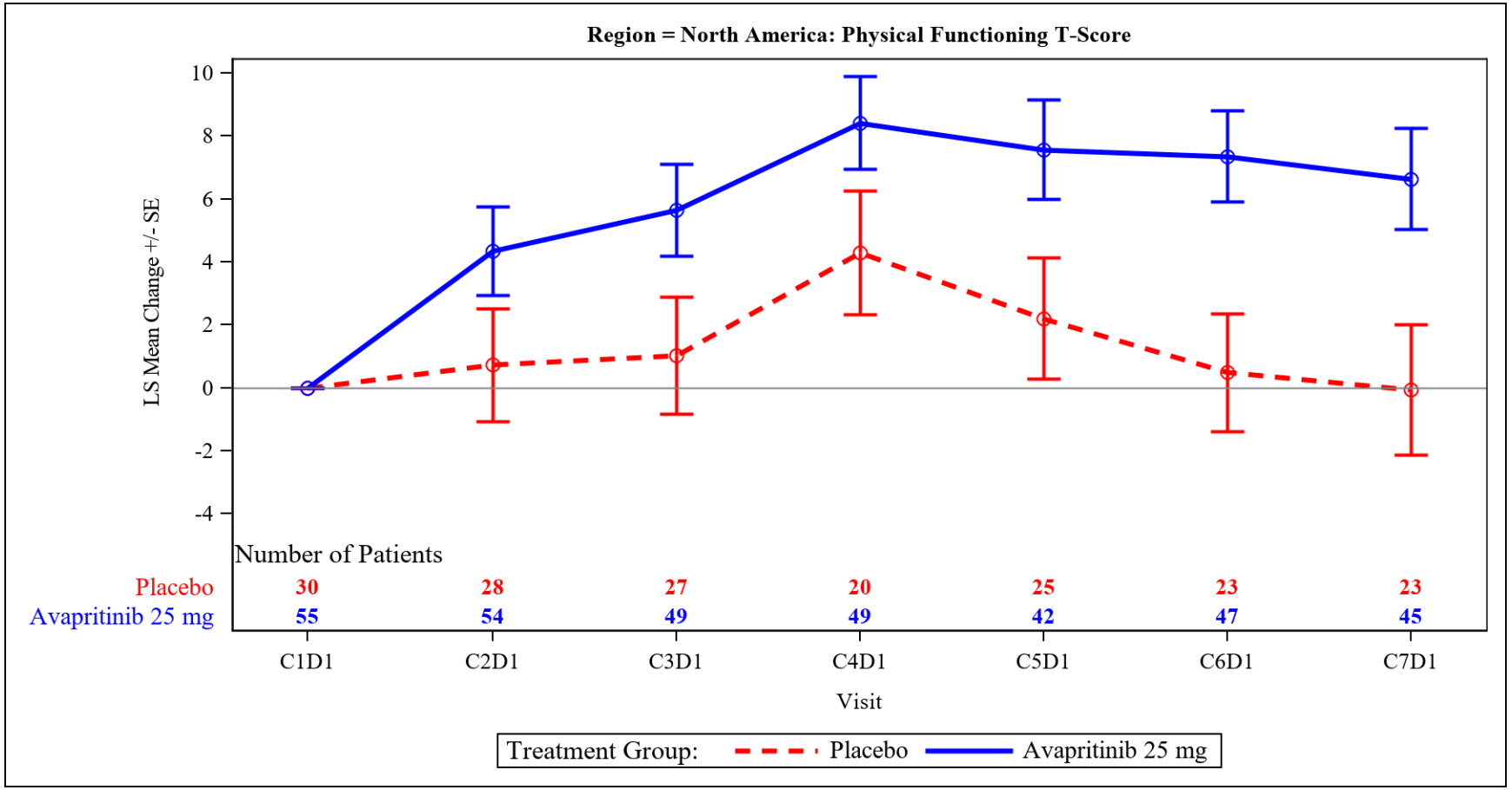
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-mcqol-ind-g-itt-reg-a.sas Date: 16:33/07AUG2023

Figure 35.2.12.1.3a
LSMean Plot of Change from Baseline in Individual MC-QoL by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)



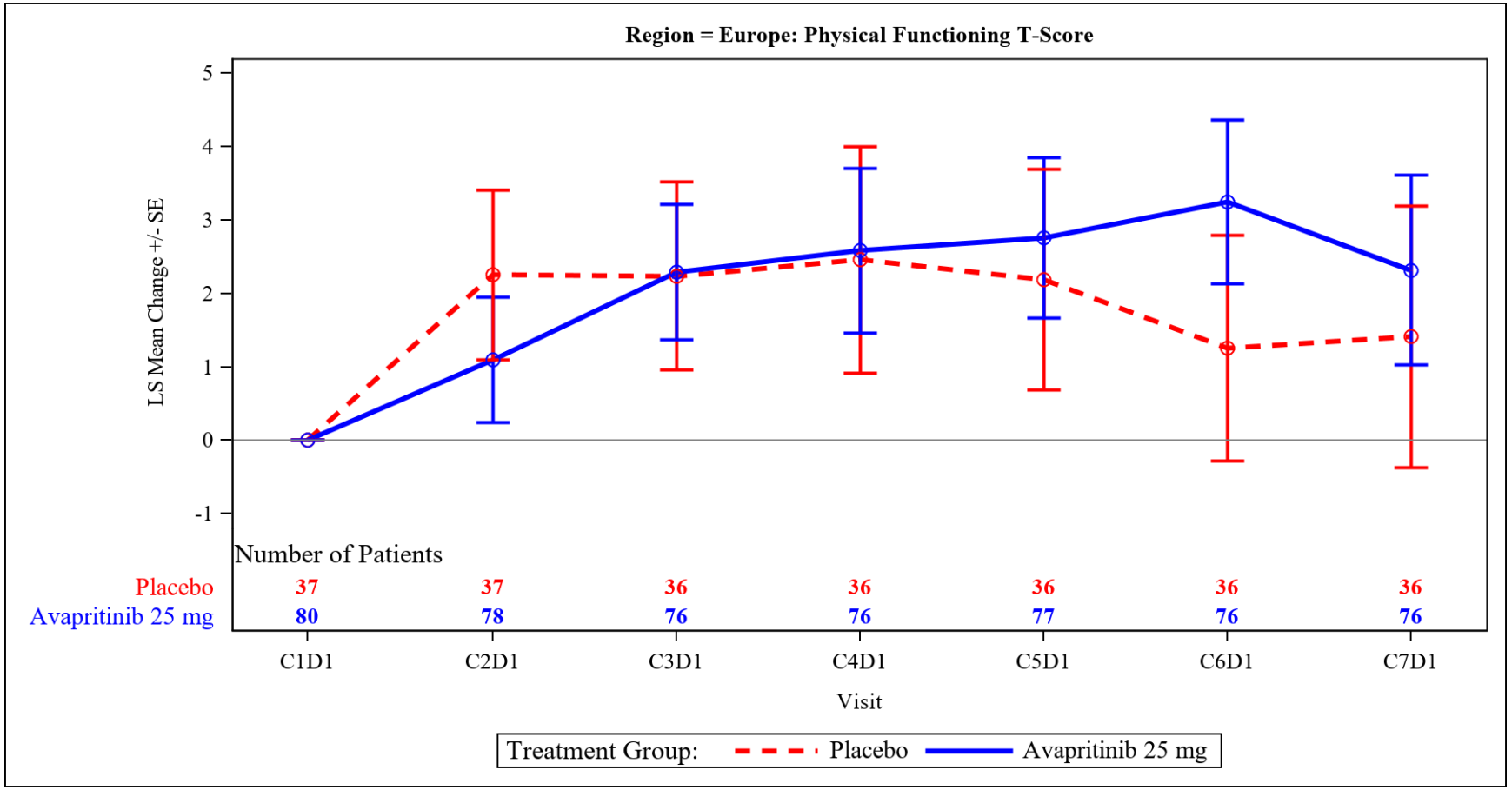
Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Figure 35.2.10.1.3a
LSMean Plot of Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-sf12-g-itt-reg-a.sas Date: 16:31/07AUG2023

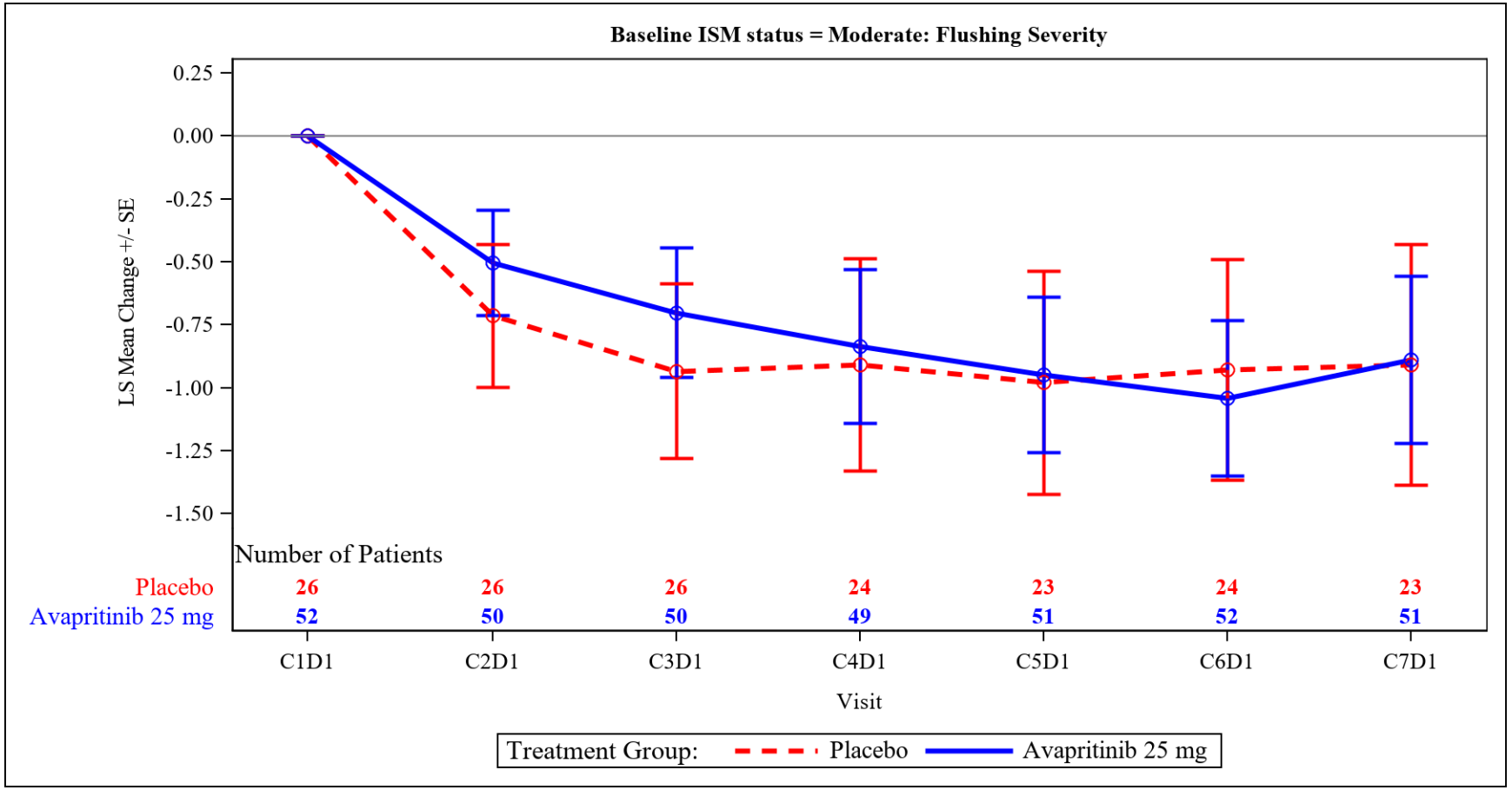
Figure 35.2.10.1.3a
LSMean Plot of Change from Baseline of SF-12 by Region
Intent-to-Treat Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-sf12-g-itt-reg-a.sas Date: 16:31/07AUG2023

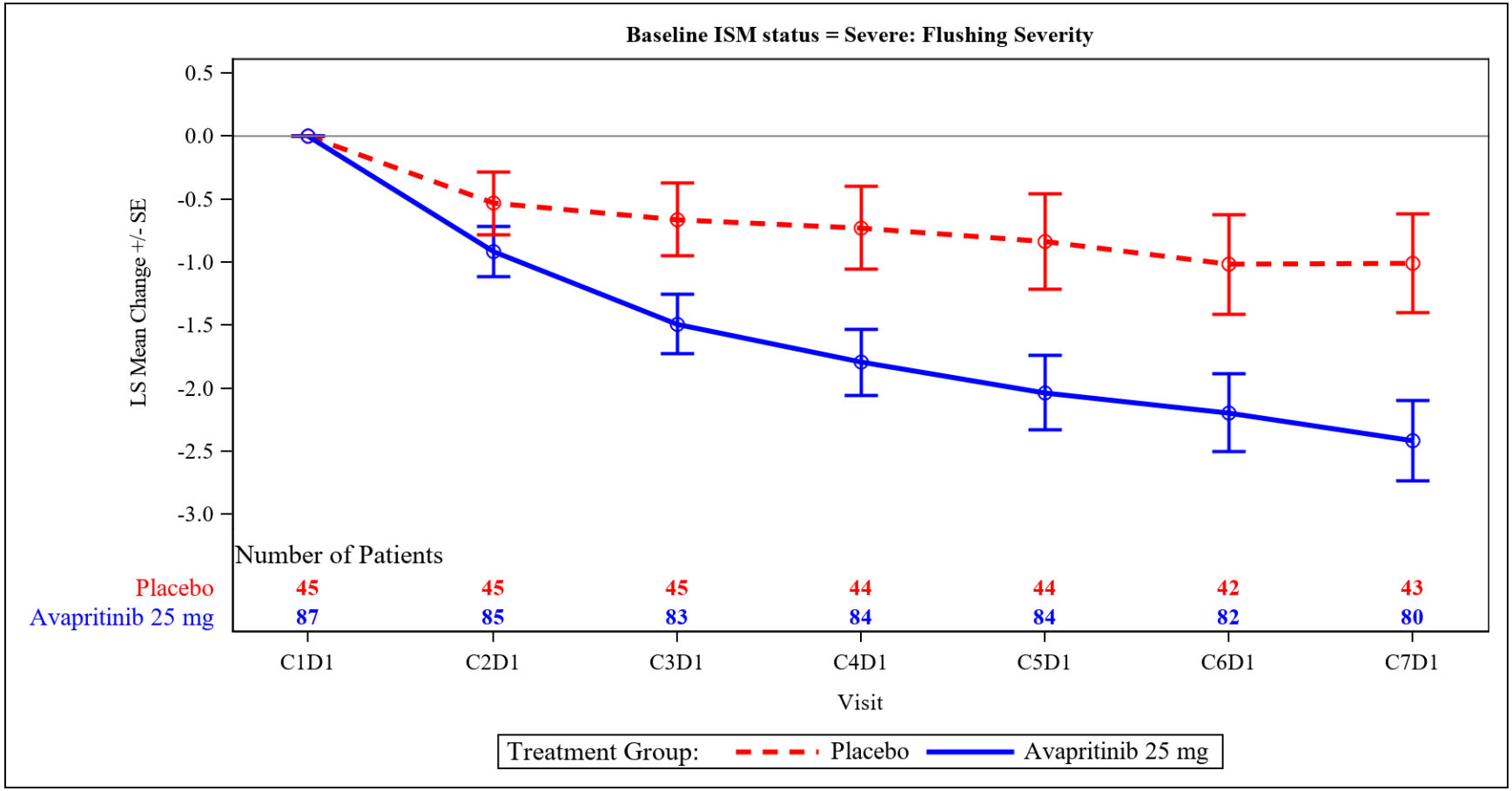
Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Figure 35.2.2.3.1.5a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)



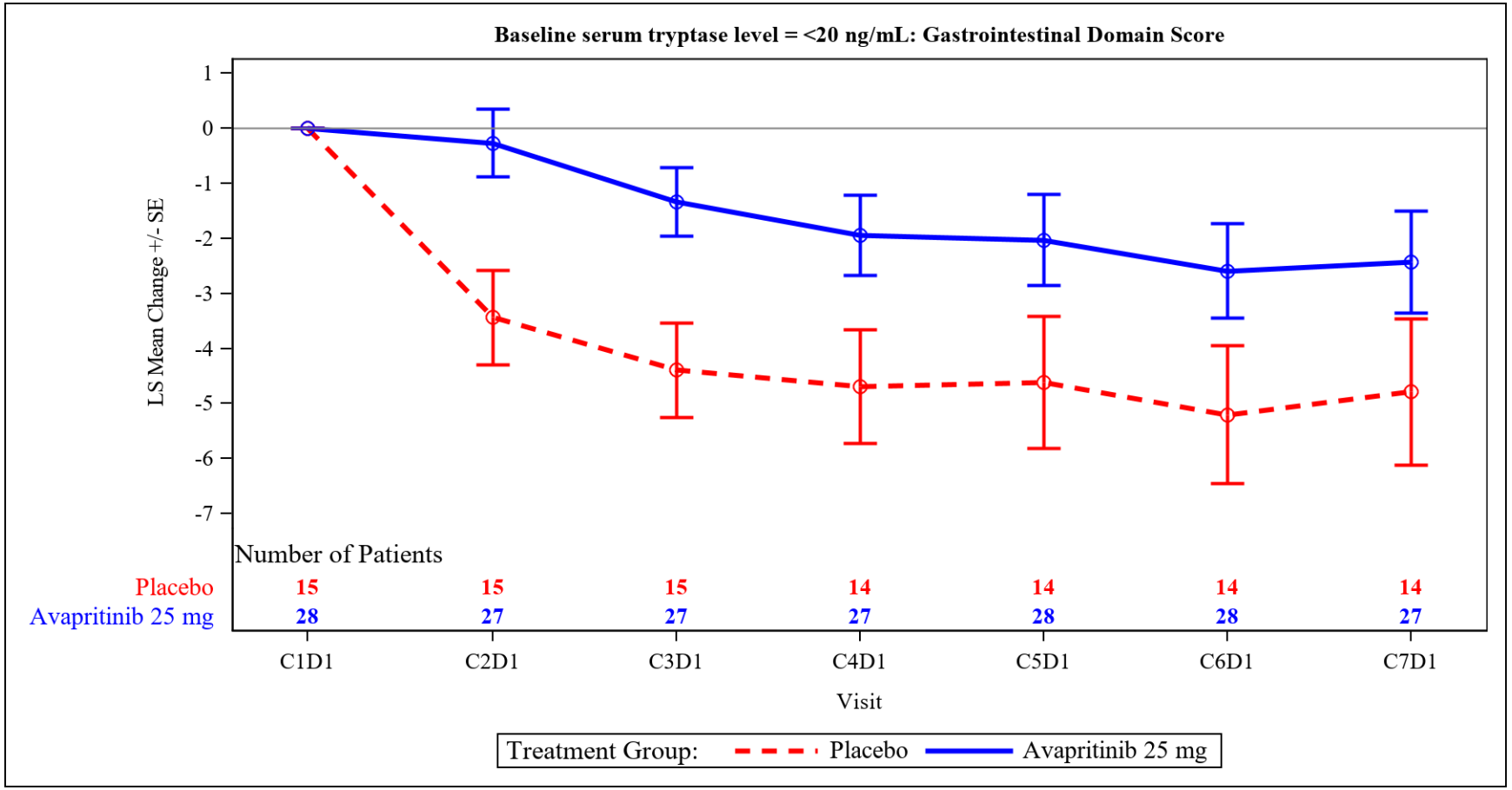
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-ismsaf-ind-sum-g-itt-ism-a.sas Date: 16:22/07AUG2023

Figure 35.2.2.3.1.5a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline ISM Status
Intent-to-Treat Population , Part 2 (Part 2 Baseline)



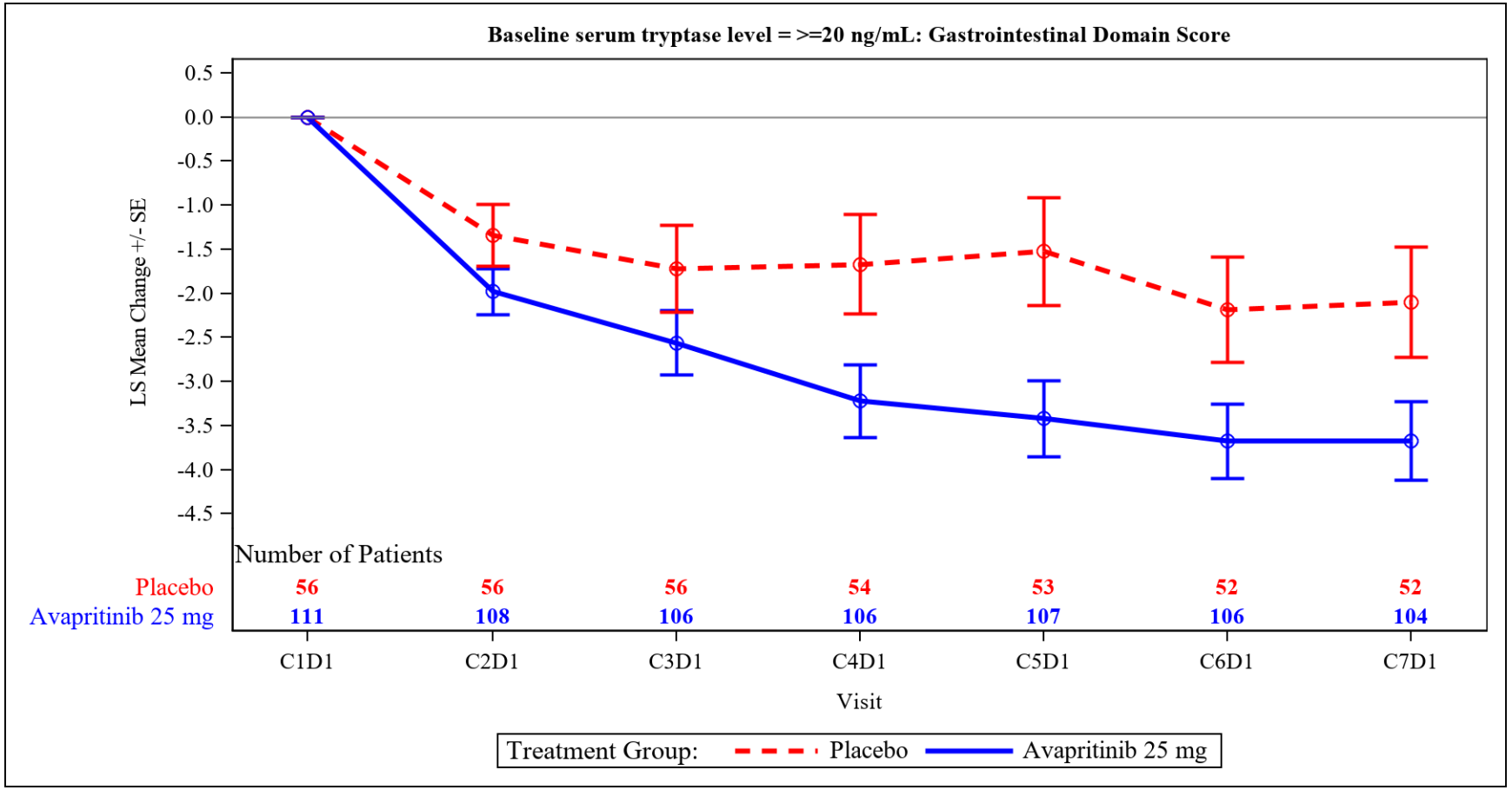
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-ismsaf-ind-sum-g-itt-ism-a.sas Date: 16:22/07AUG2023

Figure 35.2.2.2.1.6a
LSMean Plot of Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-ismsaf-dom-sum-g-itt-tryp-a.sas Date: 16:18/07AUG2023

Figure 35.2.2.2.1.6a
LSMean Plot of Change from Baseline in Domain Scores and Neurocognitive Symptom Cluster of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-ismsaf-dom-sum-g-itt-tryp-a.sas Date: 16:18/07AUG2023

Figure 35.2.2.3.1.6a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

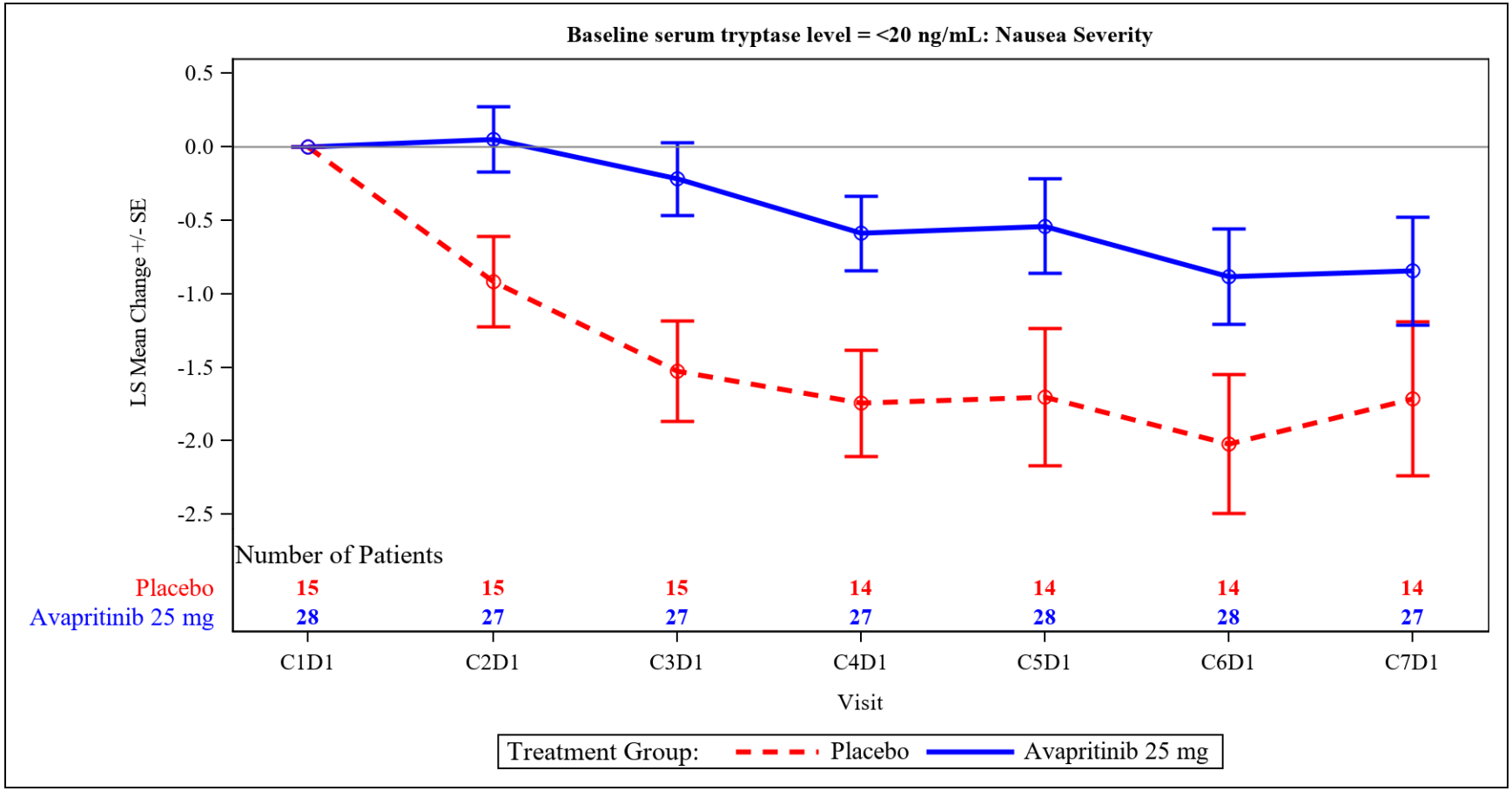
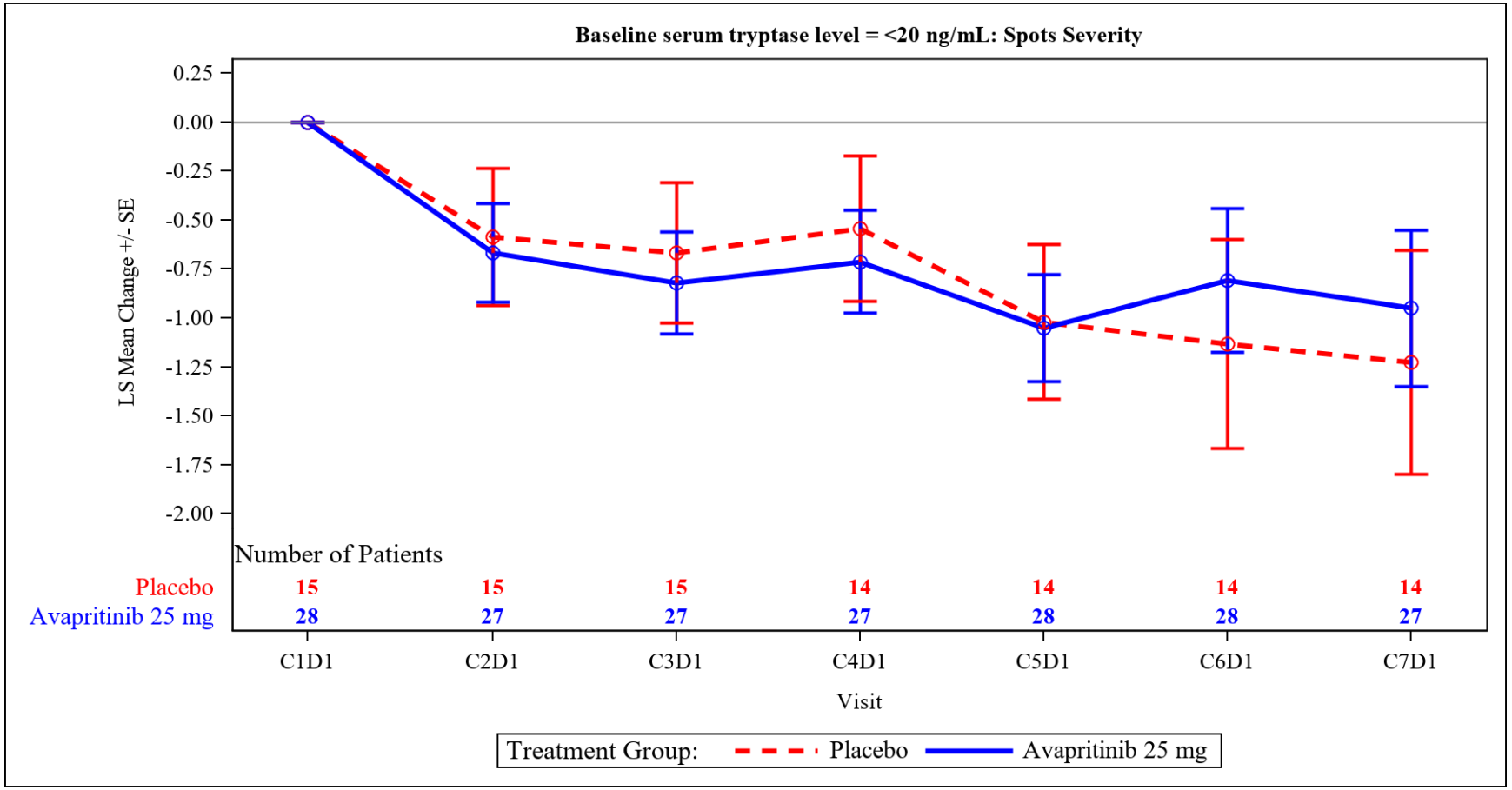


Figure 35.2.2.3.1.6a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 16:23/07AUG2023

Figure 35.2.2.3.1.6a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)

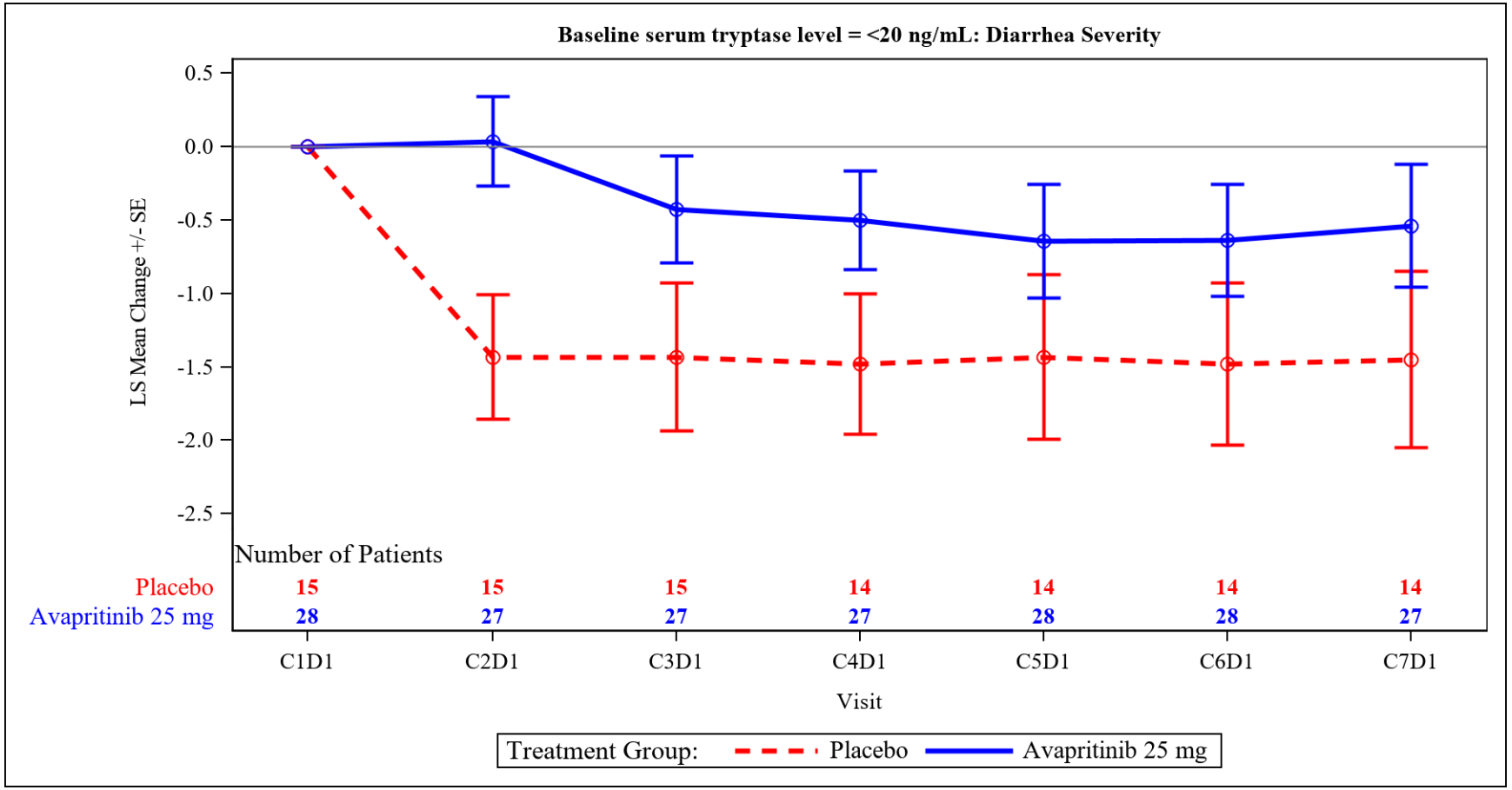
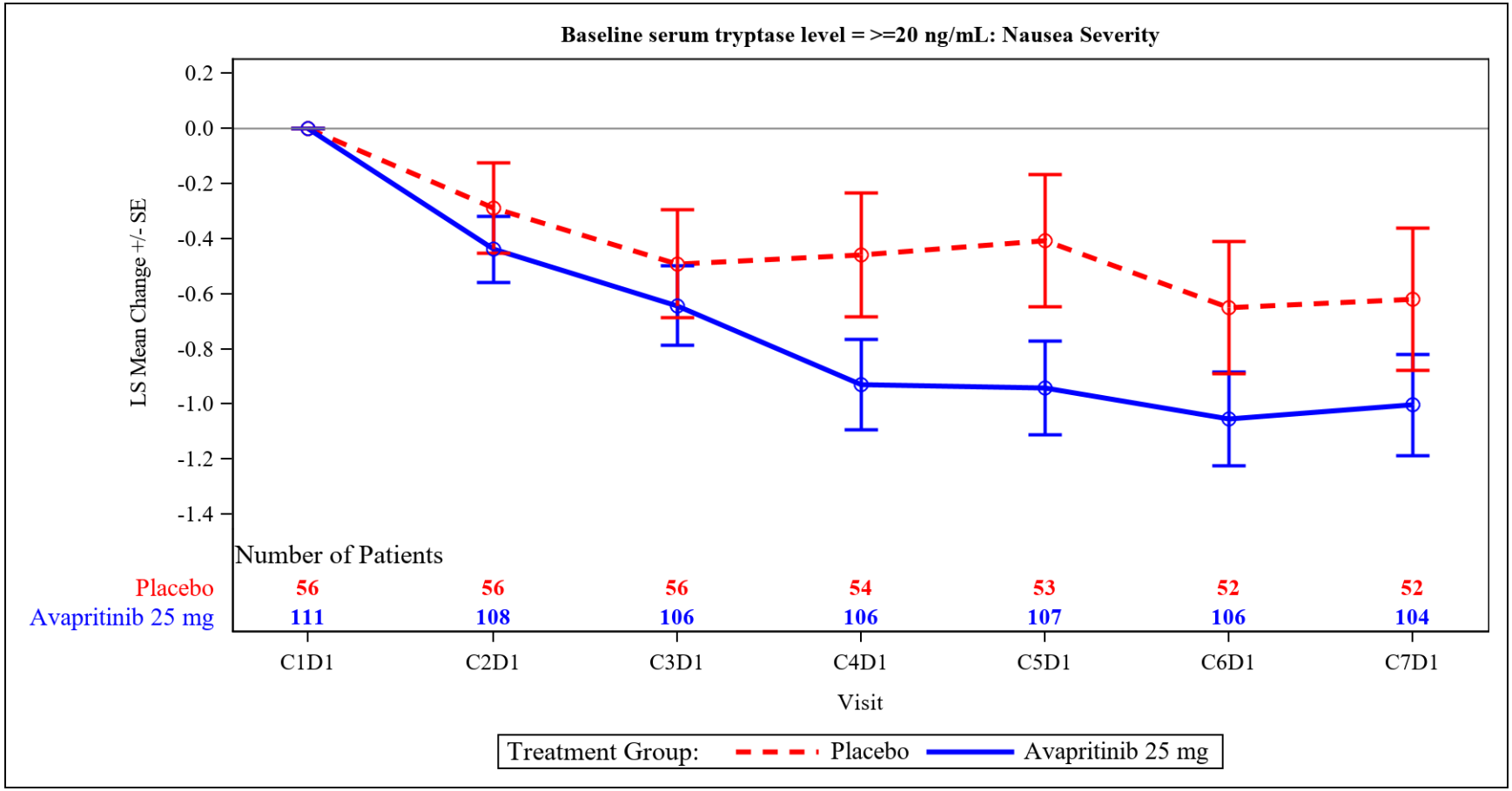
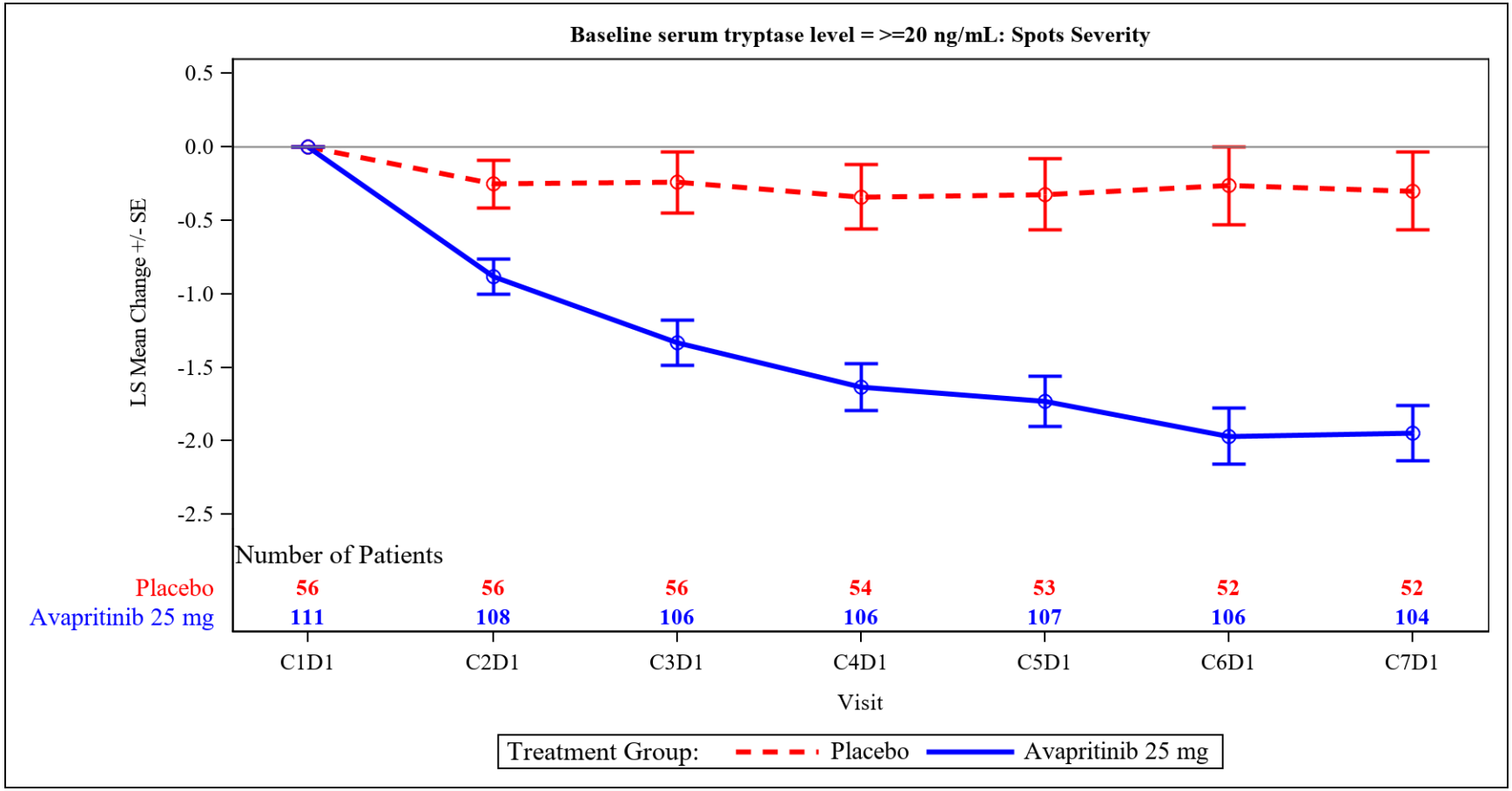


Figure 35.2.2.3.1.6a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)



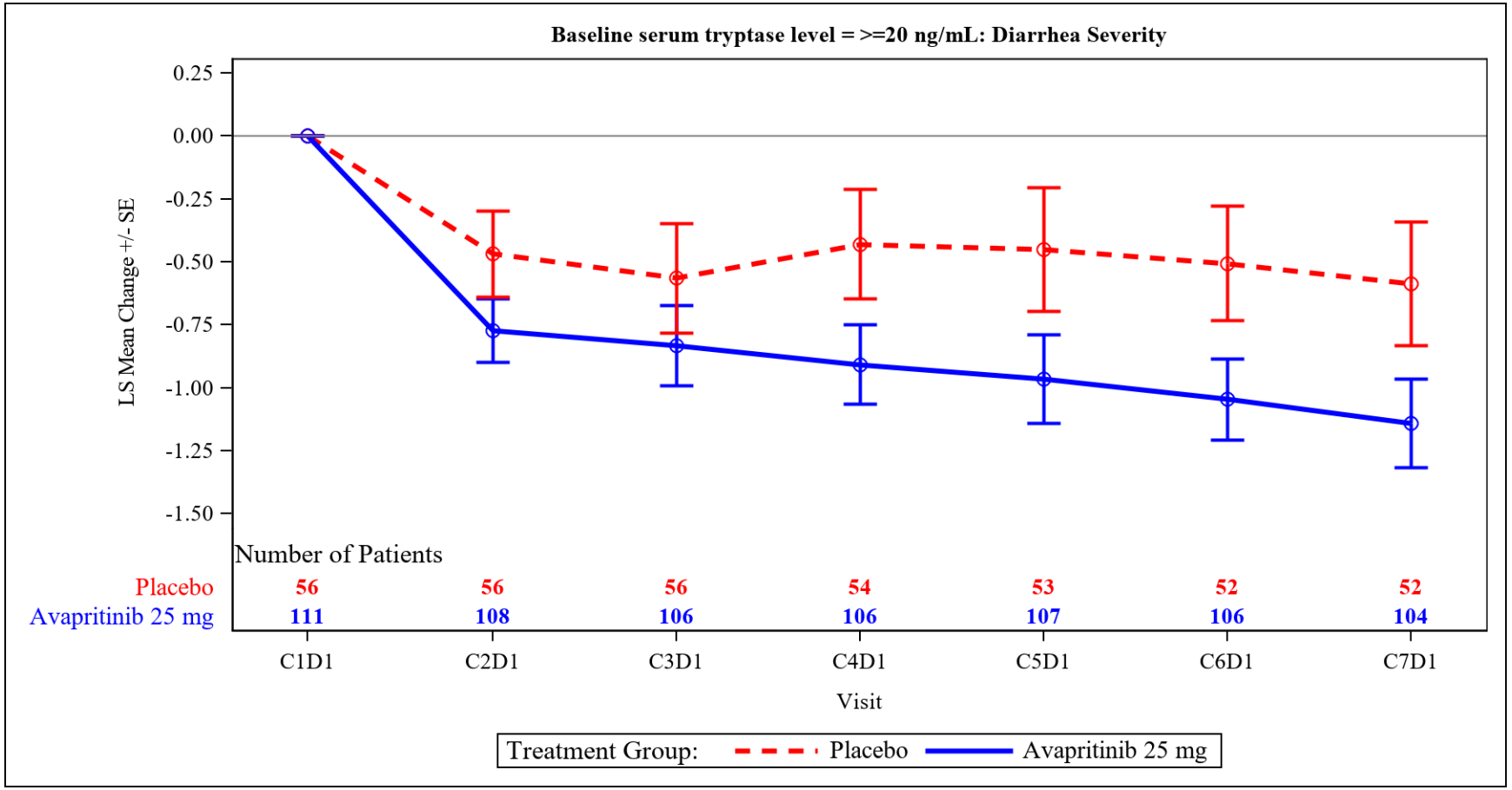
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 16:23/07AUG2023

Figure 35.2.2.3.1.6a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 16:23/07AUG2023

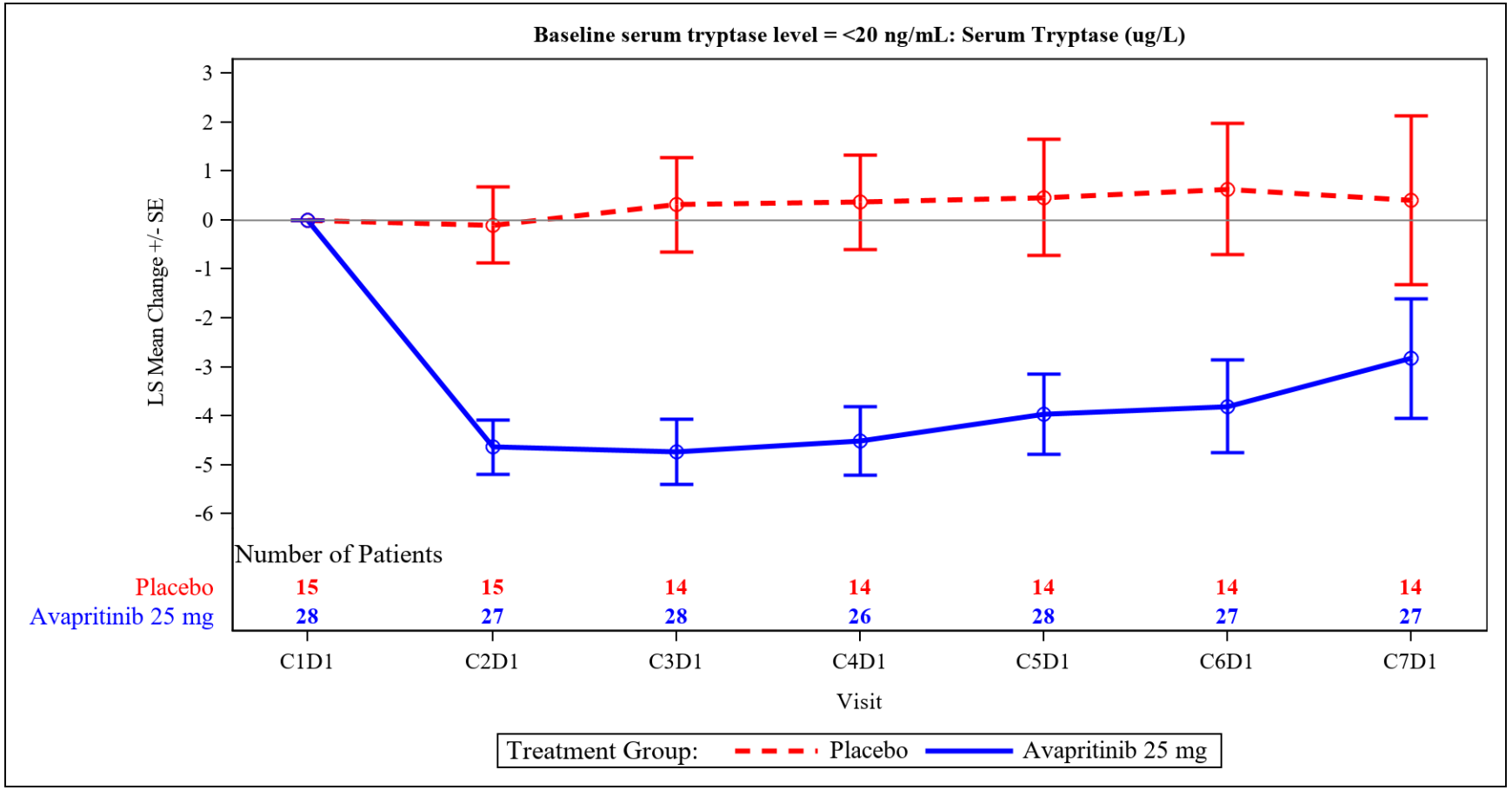
Figure 35.2.2.3.1.6a
LSMean Plot of Change from Baseline in Individual Symptom Scores of the ISM-SAF by Baseline Serum Tryptase Level
Intent-to-Treat Population , Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-ismsaf-ind-sum-g-itt-tryp-a.sas Date: 16:23/07AUG2023

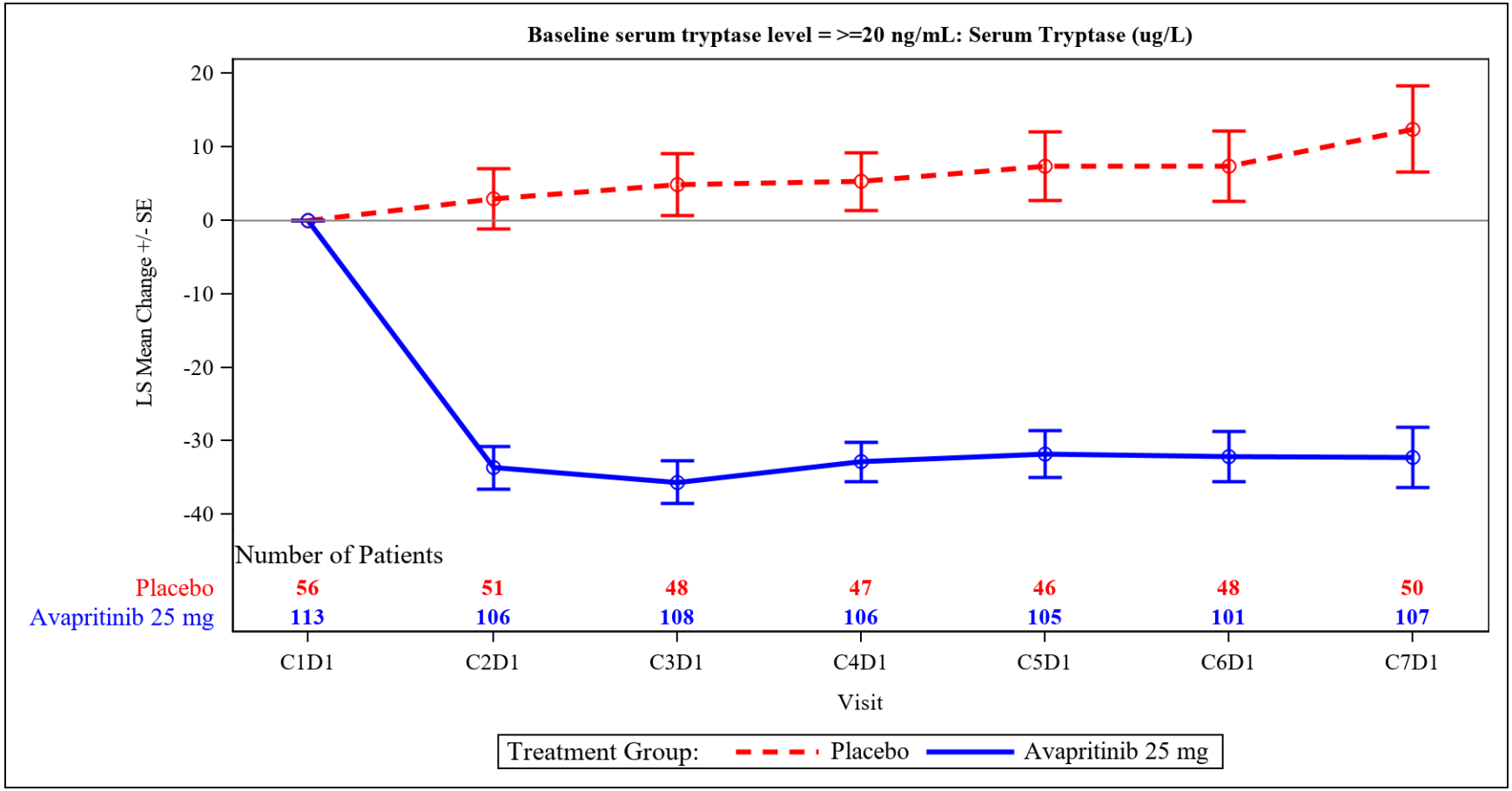
Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Figure 35.2.3.2.1.6a
LSMean Plot of Change from Baseline in Serum Tryptase (ng/mL) by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-tryp-sum-g-itt-tryp-a.sas Date: 16:29/07AUG2023

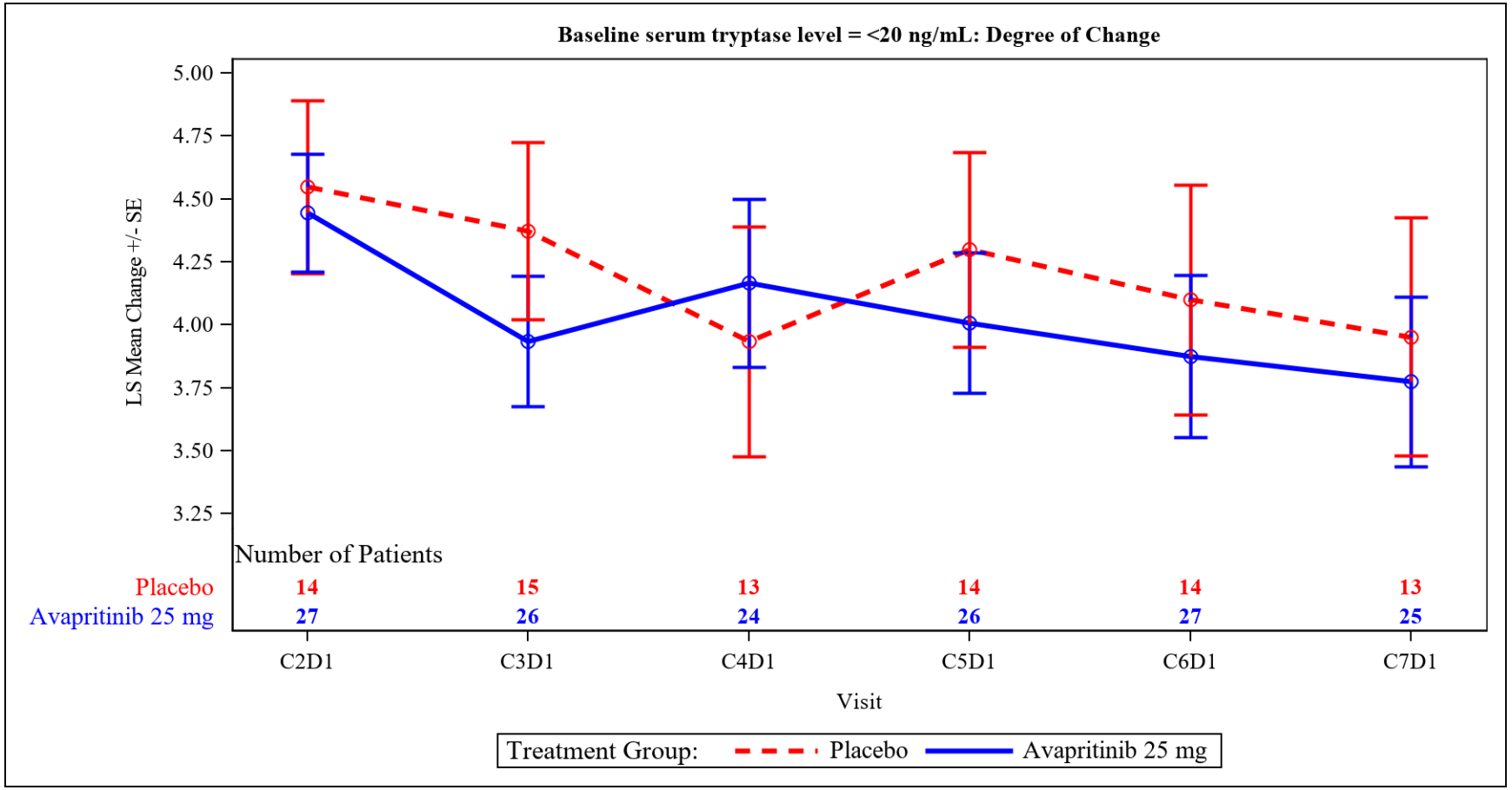
Figure 35.2.3.2.1.6a
LSMean Plot of Change from Baseline in Serum Tryptase (ng/mL) by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-tryp-sum-g-itt-tryp-a.sas Date: 16:29/07AUG2023

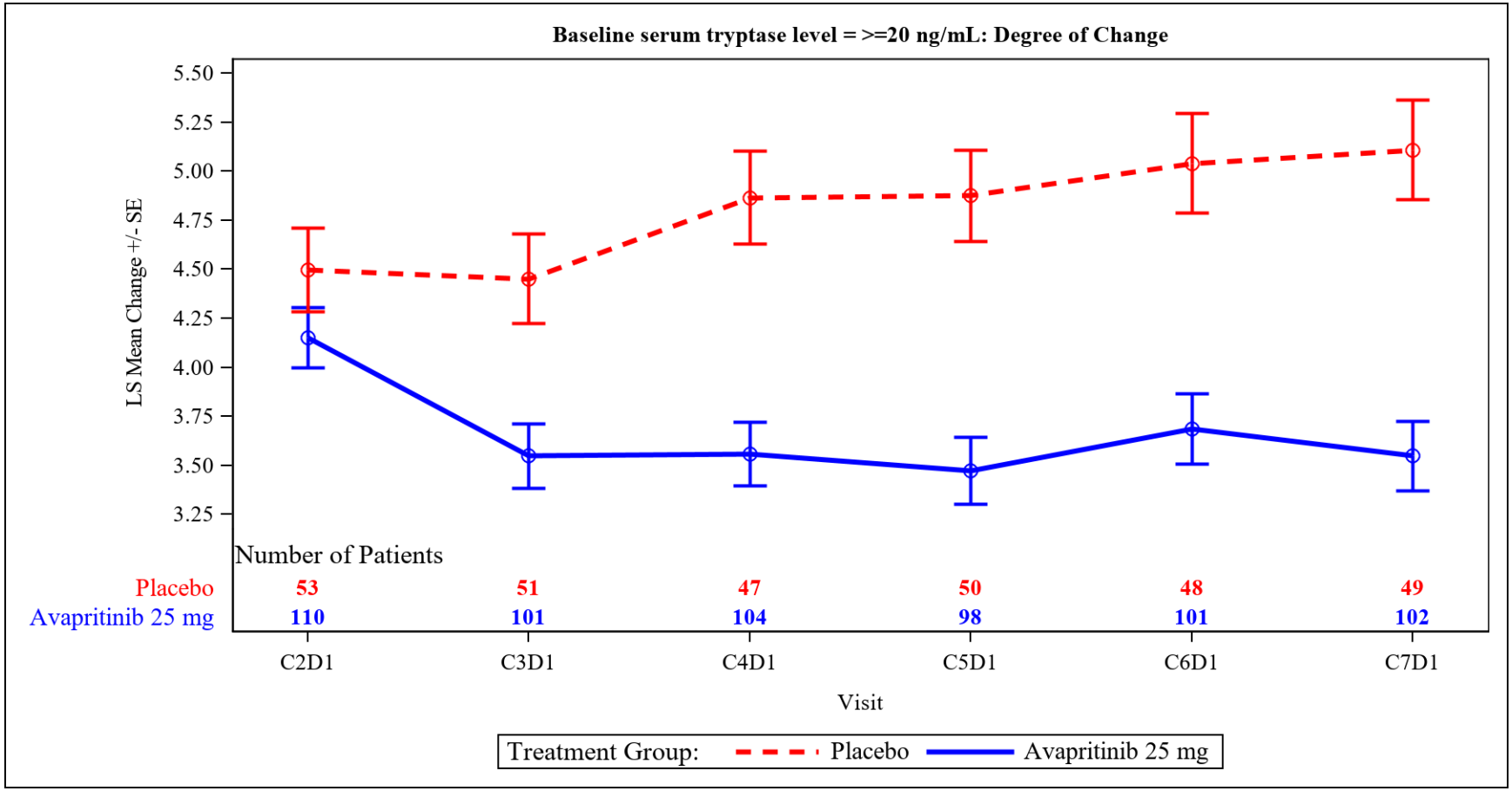
Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Figure 35.2.7.1.6a
LSMean Plot of PGIC by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)



Patient Global Impression of Change Scale: 1=No change, 2=Almost the same, 3=A little better, 4=Somewhat better, 5=Moderately Better, 6=Better, 7=A great deal better.
Degree of Change is in the range of 0 to 10, with 0 = much better and 10 = much worse.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-pgic-sum-g-itt-tryp-a.sas Date: 16:30/07AUG2023

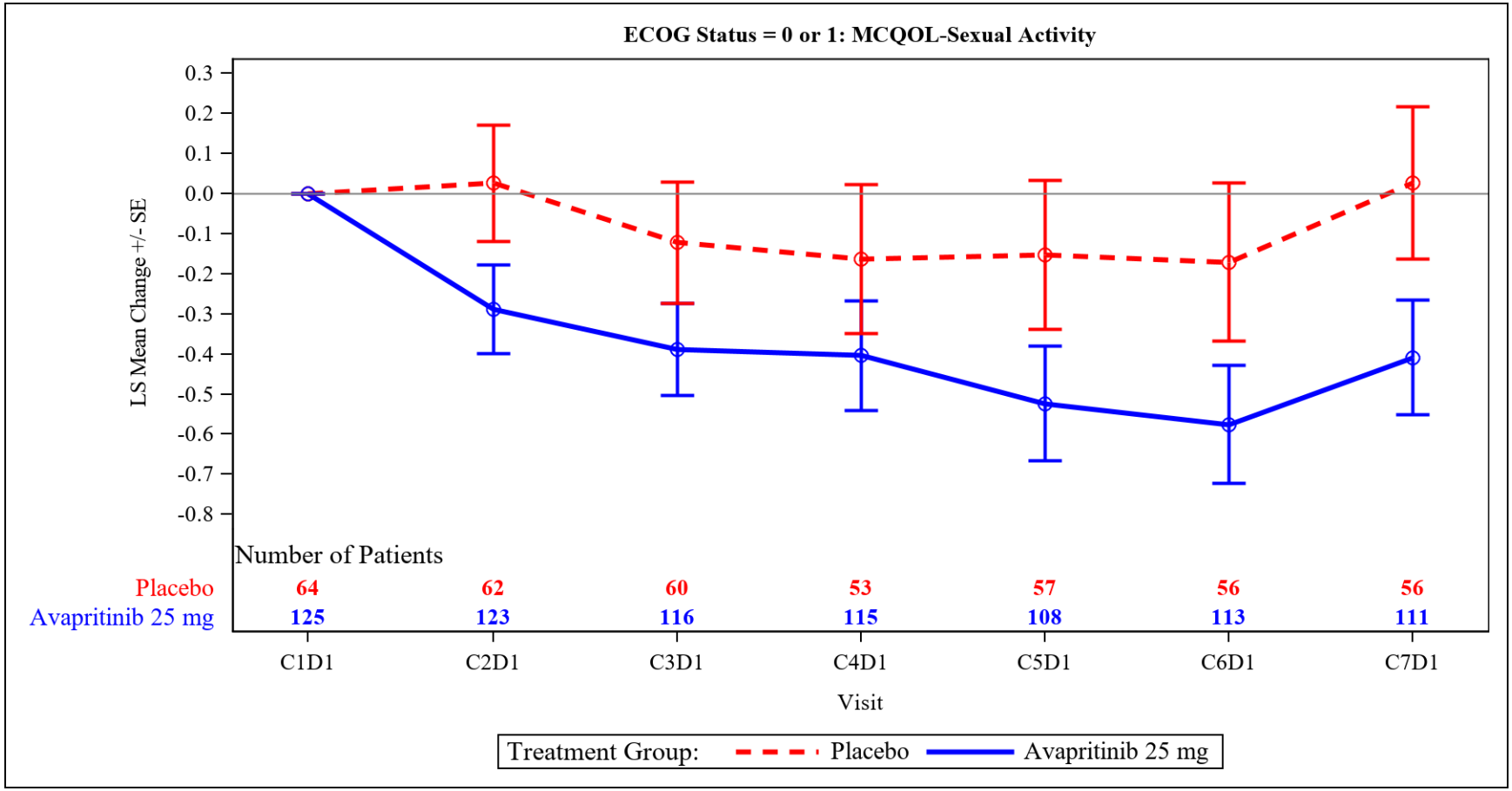
Figure 35.2.7.1.6a
LSMean Plot of PGIC by Baseline Serum Tryptase Level
Intent-to-Treat Population, Part 2 (Part 2 Baseline)



Patient Global Impression of Change Scale: 1=No change, 2=Almost the same, 3=A little better, 4=Somewhat better, 5=Moderately Better, 6=Better, 7=A great deal better.
Degree of Change is in the range of 0 to 10, with 0 = much better and 10 = much worse.
Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-pgic-sum-g-itt-tryp-a.sas Date: 16:30/07AUG2023

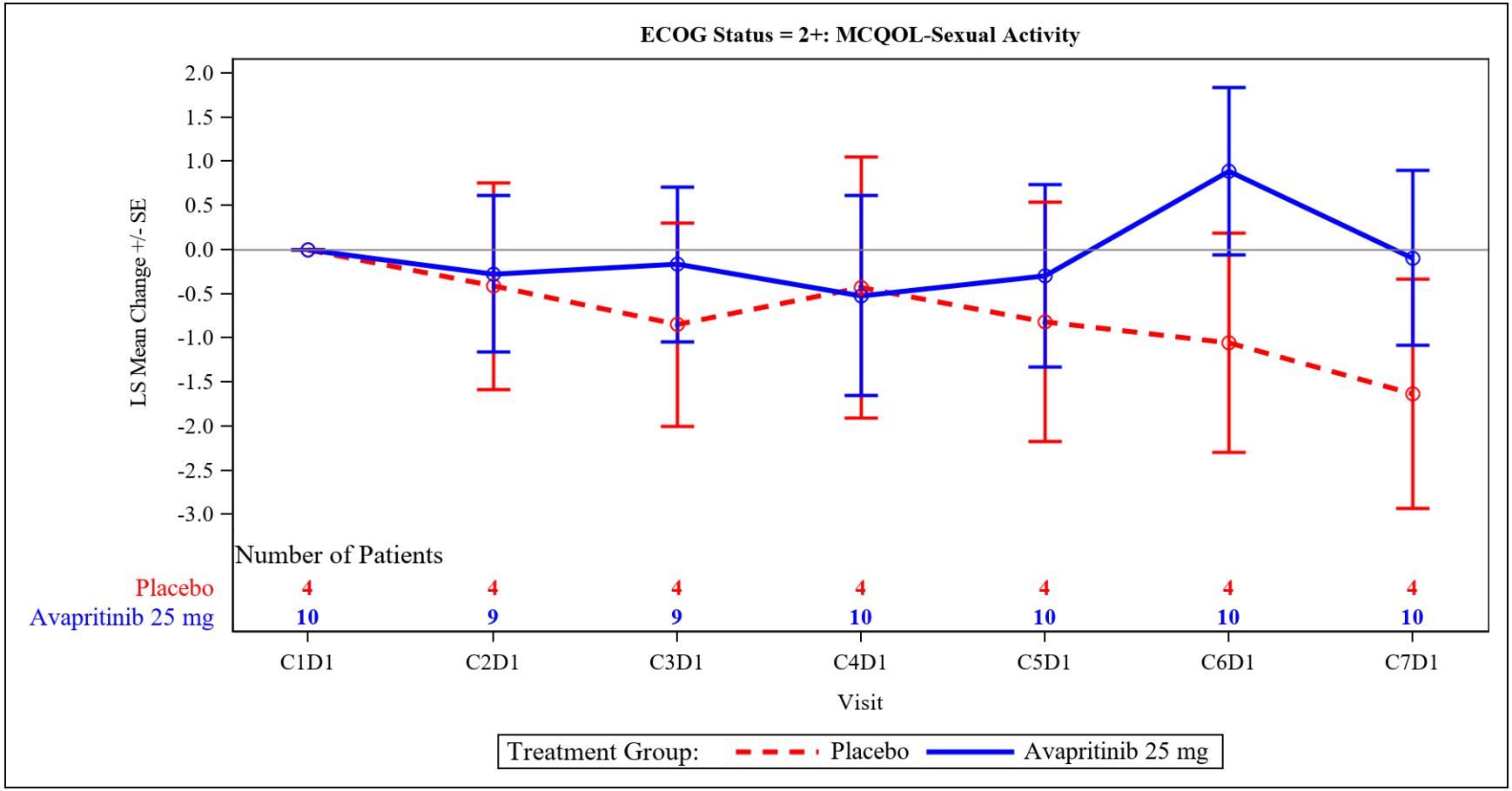
Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Figure 35.2.12.1.7a
LSMean Plot of Change from Baseline in Individual MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-mcqol-ind-g-itt-ecog-a.sas Date: 16:33/07AUG2023

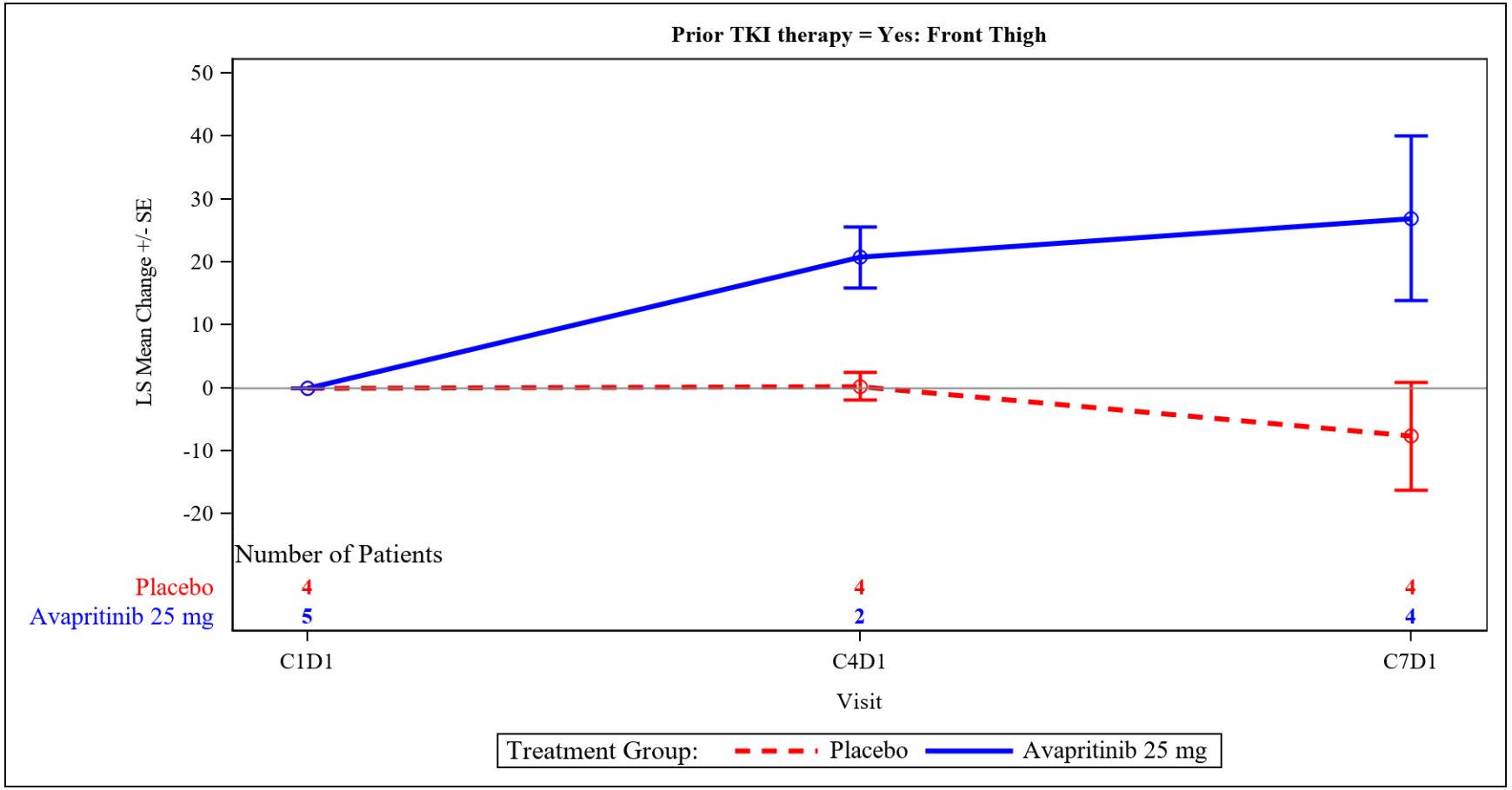
Figure 35.2.12.1.7a
LSMean Plot of Change from Baseline in Individual MC-QoL by ECOG Status
Intent-to-Treat Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-mcqol-ind-g-itt-ecog-a.sas Date: 16:33/07AUG2023

Blueprint Medicines
Protocol: BLU-285-2203
CSR Germany

Figure 35.2.11.4.1.8a
LSMean Plot of Mastocytosis in Skin by Prior TKI Therapy
Safety Population, Part 2 (Part 2 Baseline)



Program: ../BLU-285/2203_Blinded/CSR/Final/Programs/prod/adhoc/Germany/f-mast-skin-g-saf-thpy-a.sas Date: 16:32/07AUG2023

Figure 35.2.11.4.1.8a
LSMean Plot of Mastocytosis in Skin by Prior TKI Therapy
Safety Population, Part 2 (Part 2 Baseline)